

# The ICMSF Spreadsheet Tool

## Example *Campylobacter* performance

Marcel Zwietering

Wageningen University

*ICMSF Member since 2005*



# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

What is the performance of this plan for  $c=15$  (2020), and  $c=10$  (2025)

# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

Performance is defined as the arithmetic mean concentration that is detected with 95% probability for lots with standard deviation = 0.8 log cfu/g

# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

Is it quantitative/qualitative



# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

It is quantitative (limit  $m= 1000$  cfu/g)

# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=20$ , when this criterion was first implemented

Is it 2-class ? 3-class ?



# Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

What was the performance of this plan for  $c=10$ , when this criterion was first implemented

Is it 2-class (only one limit  $m$ )



# Sampling plan: Process Hygiene

Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

Which tab now to select ?



2-class enrichment

2-class counts

3-class counts

3-class mixed

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

# Sampling plan: Process Hygiene

Hygiene criterion *Campylobacter* broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	20*	1000 cfu/g	-	ISO 10272-2

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

2-class enrichment

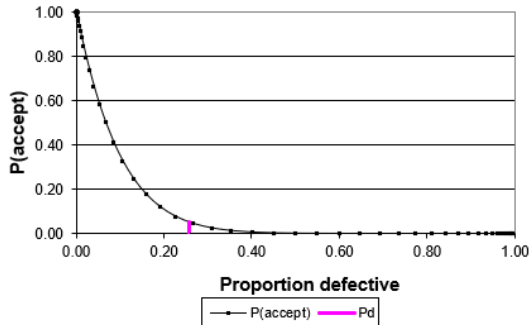
**2-class counts**

3-class counts

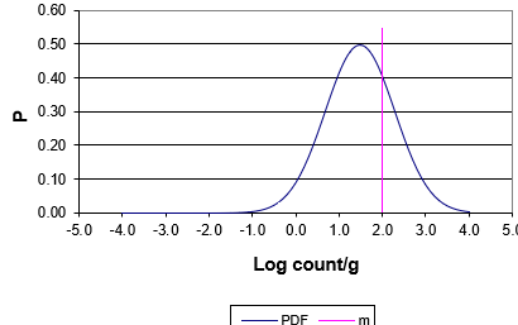
3-class mixed

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

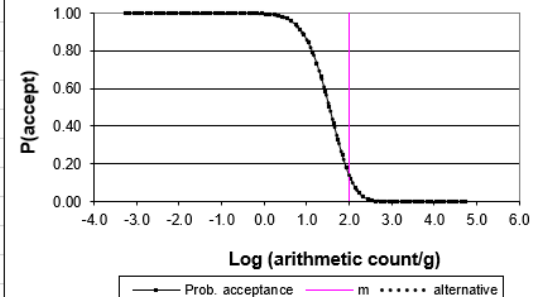
Operating characteristic curve for proportion defective, with  $n=10$  and  $c=0$



Probability density function (PDF) for log counts. Distribution mean = 1.48 and sigma = 0.80



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



Lot acceptance for Pd		P(accept)
Pd	10 %	34.9 %
actualPd	25.9 %	5.00 %

INPUTS		P(accept)	
mean	1.48	Computed	5.00 %
sigma	0.80	Desired	5 %
m	2	Find mean that gives desired P(accept)	
n	10	Find n that gives desired P(accept) or better (less)	
c	0	P(reject) 95.00 %	

ALTERNATIVE n AND c		P(accept)	
mean	1.48	Computed	5.00 %
sigma	0.80	Target, left	5.00 %
m	2	For any value of n and c imputed find the m that gives the same P(accept) as the model on the	
n	10		
c	0		

Sandbox: for your own calculations			
FSO	3		
compliant	0.971076	not comply	0.028924
%	97.10758 %		2.892418

Means	
Arithmetic (=Average)	Geometric (=Median)
165.7 cfu/g	30.4 cfu/g
2.22 log cfu/g	1.48 log cfu/g

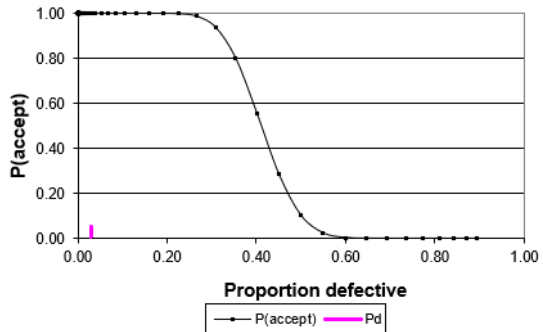
Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	3.96
FSO	P(exceedance)	target level
3.96	0.000973	1.482524

This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 30.4 cfu/g and an arithmetic mean concentration of 165.7 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 0 out of 10 samples having higher levels than 2 logs cfu/g)

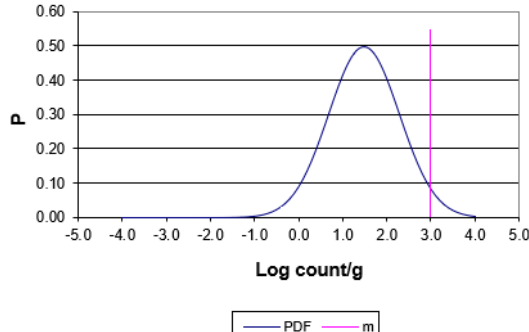
What is the performance (the arithmetic mean concentration detected with 95% probability) for  $n=50$ ,  $c=20$ ,  $m=100$  cfu/g for lots with standard deviation = 0.8 log cfu/g?



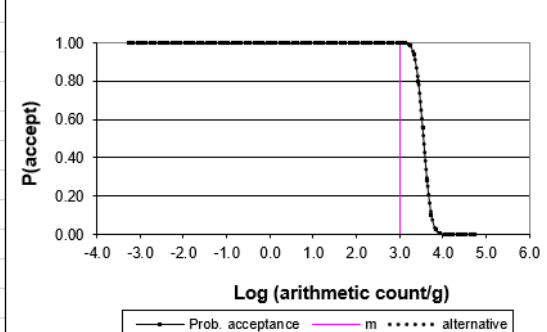
Operating characteristic curve for proportion defective, with  $n=50$  and  $c=20$



Probability density function (PDF) for log counts. Distribution mean = 1.48 and sigma = 0.80



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



Lot acceptance for Pd		P(accept)
Pd	10 %	100.0 %
actualPd	2.9 %	100.00 %

INPUTS		P(accept)	
mean	1.48	Computed	100.00 %
sigma	0.80	Desired	5 %
m	3	Find mean that gives desired P(accept)	
n	50	Find n that gives desired P(accept) or better (less)	
c	20	P(reject)	0.00 %

ALTERNATIVE n AND c		P(accept)	
mean	1.48	Computed	100.00 %
sigma	0.80	Target, left	100.00 %
m	3	For any value of n and c imputed find the m that gives the same P(accept) as the model on the	
n	50		
c	20		

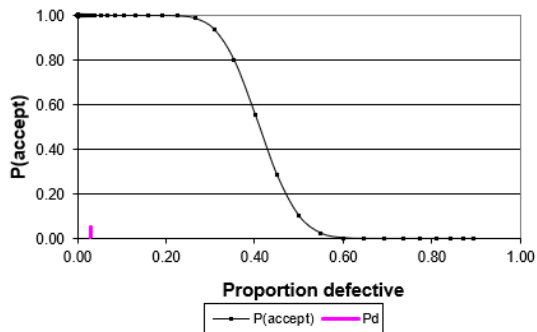
Sandbox: for your own calculations			
FSO	3		
compliant	0.971076	not comply	0.028924
%	97.10758 %		2.892418

Means	
Arithmetic (=Average)	Geometric (=Median)
165.7 cfu/g	30.4 cfu/g
2.22 log cfu/g	1.48 log cfu/g

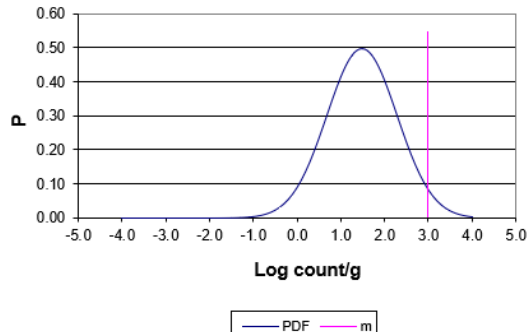
Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	3.96
FSO	P(exceedance)	target level
3.96	0.000973	1.482524

$\sigma=0.8, m=3, n=50, c=20$   
 Desired  $P(\text{accept}) = 5\%$  ( $95\% P(\text{reject})$ )

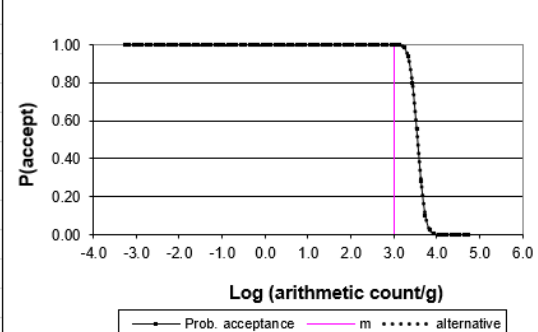
Operating characteristic curve for proportion defective, with  $n=50$  and  $c=20$



Probability density function (PDF) for log counts. Distribution mean = 1.48 and sigma = 0.80



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



Lot acceptance for Pd		
Pd	10 %	P(accept) 100.0 %
actualPd	2.9 %	100.00 %

INPUTS		P(accept)	
mean	1.48	Computed	100.00 %
sigma	0.80	Desired	5 %
m	3	Find mean that gives desired P(accept)	
n	50	Find n that gives desired P(accept) or better (less)	
c	20	P(reject)	0.00 %

ALTERNATIVE n AND c		P(accept)	
mean	1.48	Computed	100.00 %
sigma	0.80	Target, left	100.00 %
m	3	For any value of n and c imputed find the m that gives the same P(accept) as the model on the	
n	50		
c	20		

Sandbox: for your own calculations		
FSO	3	
compliant	0.971076	not comply 0.028924
%	97.10758 %	2.892418

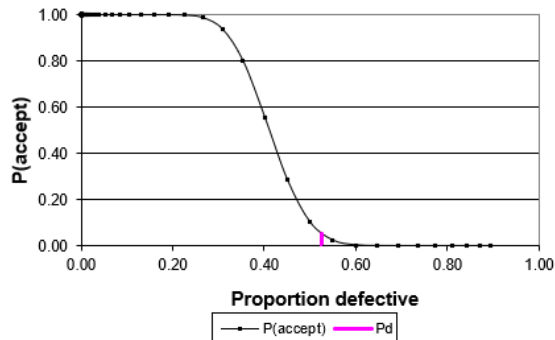
Means	
Arithmetic (=Average)	Geometric (=Median)
165.7 cfu/g	30.4 cfu/g
2.22 log cfu/g	1.48 log cfu/g

Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	3.96
FSO	P(exceedance)	target level
3.96	0.000973	1.482524

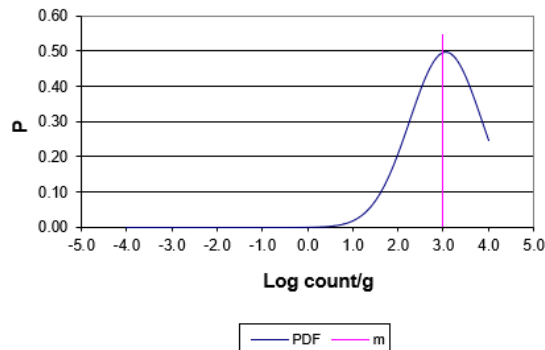
$\sigma=0.8, m=3, n=50, c=20$   
 Desired  $P(\text{accept}) = 5\%$  ( $95\% P(\text{reject})$ )

Find mean that gives desired  $P(\text{accept})$

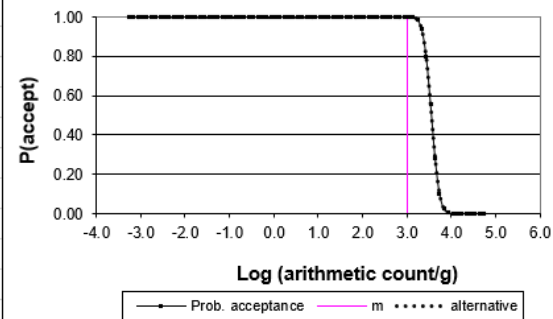
**Operating characteristic curve for proportion defective, with n=50 and c=20**



**Probability density function (PDF) for log counts. Distribution mean = 3.05 and sigma = 0.80**



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



**Lot acceptance for Pd**

Pd	10 %	P(accept)	100.0 %
actualPd	52.6 %		5.00 %

**INPUTS**

mean	3.05
sigma	0.80
m	3
n	50
c	20

**P(accept)**

Desired	5 %
Find mean that gives desired P(accept)	
Find n that gives desired P(accept) or better (less)	
P(reject)	95.00 %

**ALTERNATIVE n AND c**

mean	3.05
sigma	0.80
m	3
n	50
c	20

**P(accept)**

Computed	5.00 %
Target, left	5.00 %
For any value of n and c imputed find the m that gives the same P(accept) as the model on the	

**Sandbox: for your own calculations**

FSO	3	
compliant	0.47388 not comply	0.52612
%	47.38798 %	52.61202

**Means**

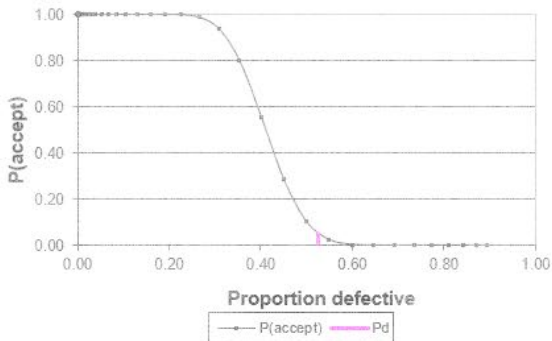
Arithmetic (=Average)		Geometric (=Median)	
6155.2	cfu/g	1128.3	cfu/g
3.79	log cfu/g	3.05	log cfu/g

**Implied Acceptance level**

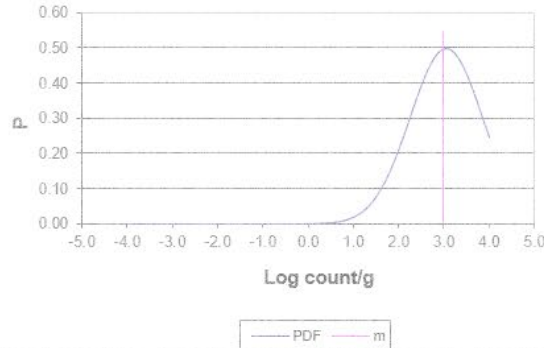
Percentile	z-score	Concentration at this percentile
99.9	3.10	5.53
FSO	P(exceedance)	target level
5.53	0.000973	3.052416

This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 1,128.3 cfu/g and an arithmetic mean concentration of 6,155.2 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 20 out of 50 samples having higher levels than 3 logs cfu/g)

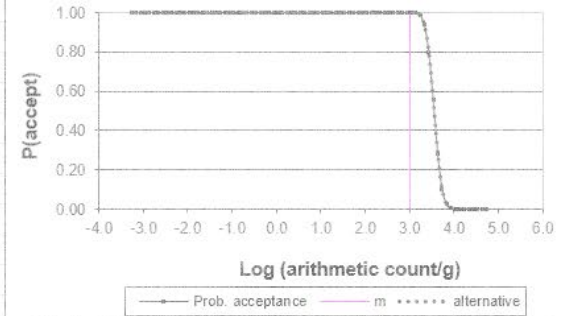
Operating characteristic curve for proportion defective, with n=50 and c=20



Probability density function (PDF) for log counts. Distribution mean = 3.05 and sigma = 0.80



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



Lot acceptance for Pd

Pd	10 %	P(accept)	100.0 %
actualPd	52.6 %		5.00 %

INPUTS

mean	3.05
sigma	0.80
m	3
n	50
c	20

P(accept)

Computed	5.00 %
Desired	5 %
Find mean that gives desired P(accept)	
Find n that gives desired P(accept) or better (less)	
P(reject)	95.00 %

ALTERNATIVE n AND c

mean	3.05
sigma	0.80
m	3
n	50
c	20

P(accept)

Computed	5.00 %
Target, left	5.00 %
For any value of n and c imputed find the m that gives the same P(accept) as the model on the	

Sandbox: for your own calculations

FSO	3		
compliant	0.47388	not comply	0.52612
%	47.38798 %		52.61202

Means

Arithmetic (=Average)		Geometric (=Median)	
6155.2	cfu/g	1128.3	cfu/g
3.79	log cfu/g	3.05	log cfu/g

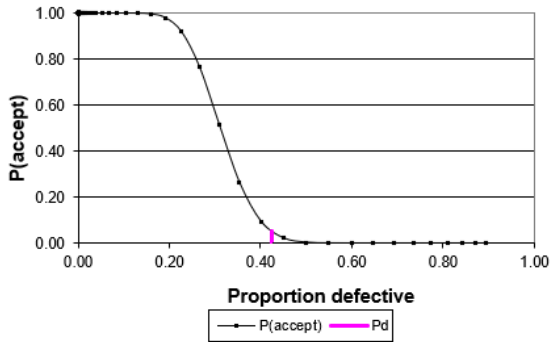
Implied Acceptance level

Percentile	z-score	Concentration at this percentile
99.9	3.10	5.53
FSO	P(exceedance)	target level
5.53	0.000973	3.052416

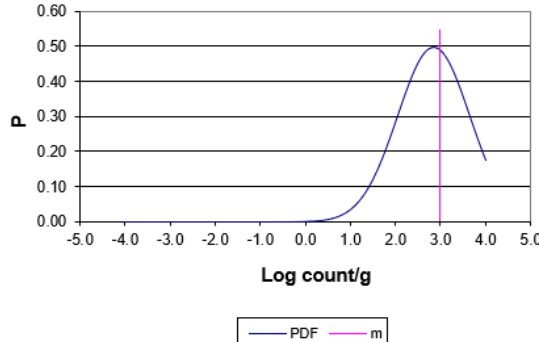
This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 1,128.3 cfu/g and an arithmetic mean concentration of 6,155.2 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 20 out of 50 samples having higher levels than 3 logs cfu/g)

This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 1128 cfu/g and an arithmetic mean concentration of 6155 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 20 out of 50 samples having higher levels than 3 logs cfu/g)

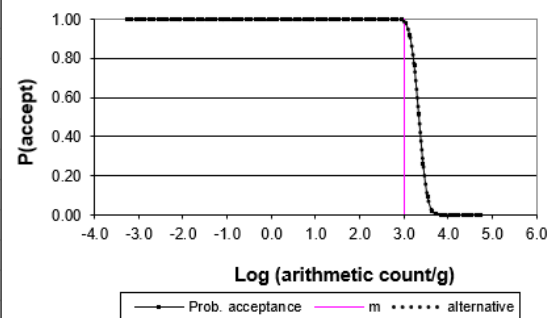
Operating characteristic curve for proportion defective, with n=50 and c=15



Probability density function (PDF) for log counts. Distribution mean = 2.85 and sigma = 0.80



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



Lot acceptance for Pd			P(accept)
Pd	10 %		100.0 %
actualPd	42.4 %		5.00 %

INPUTS		P(accept)	
mean	2.85	Computed	5.00 %
sigma	0.80	Desired	5 %
m	3	Find mean that gives desired P(accept)	
n	50	Find n that gives desired P(accept) or better (less)	
c	15	P(reject)	95.00 %

ALTERNATIVE n AND c		P(accept)	
mean	2.85	Computed	5.00 %
sigma	0.80	Target, left	5.00 %
m	3	For any value of n and c imputed find the m that gives the same P(accept) as the model on the	
n	50		
c	15		

Sandbox: for your own calculations			
FSO	3		
compliant	0.576266	not comply	0.423734
%	57.62665 %		42.37335

Means	
Arithmetic (=Average)	Geometric (=Median)
3827.8 cfu/g	701.6 cfu/g
3.58 log cfu/g	2.85 log cfu/g

Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	5.32
FSO	P(exceedance)	target level
5.32	0.000973	2.846119

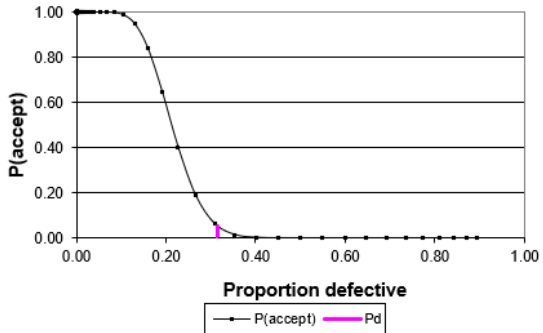


This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 701.6 cfu/g and an arithmetic mean concentration of 3,827.8 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 15 out of 50 samples having higher levels than 3 logs cfu/g)

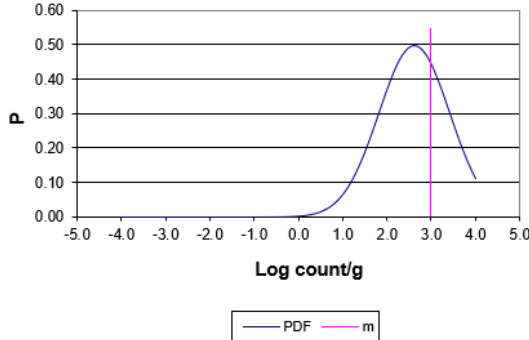
This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 702 cfu/g and an arithmetic mean concentration of 3828 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 15 out of 50 samples having higher levels than 3 logs cfu/g)



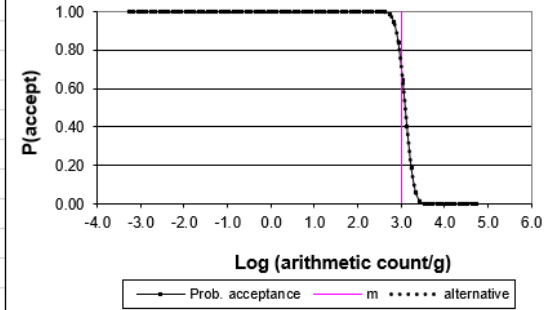
**Operating characteristic curve for proportion defective, with n=50 and c=10**



**Probability density function (PDF) for log counts. Distribution mean = 2.62 and sigma = 0.80**



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



**Lot acceptance for Pd**

		<b>P(accept)</b>
Pd	10 %	99.1 %
actualPd	31.6 %	5.00 %

**INPUTS**

mean	2.62
sigma	0.80
m	3
n	50
c	10

**P(accept)**

Computed 5.00 %

Desired 5 %

Find mean that gives desired P(accept)

Find n that gives desired P(accept) or better (less)

P(reject) 95.00 %

**ALTERNATIVE n AND c**

mean	2.62
sigma	0.80
m	3
n	50
c	10

**P(accept)**

Computed 5.00 %

Target, left 5.00 %

For any value of n and c imputed find the m that gives the same P(accept) as the model on the

**Sandbox: for your own calculations**

FSO	3	
compliant	0.684404	not comply 0.315596
%	68.44038 %	31.55962

**Means**

Arithmetic (=Average)		Geometric (=Median)	
2253.1	cfu/g	413.0	cfu/g
3.35	log cfu/g	2.62	log cfu/g

**Implied Acceptance level**

Percentile	z-score	Concentration at this percentile
99.9	3.10	5.09
FSO	P(exceedance)	target level
5.09	0.000973	2.615961

This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 413.0 cfu/g and an arithmetic mean concentration of 2,253.1 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 10 out of 50 samples having higher levels than 3 logs cfu/g)

This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 413 cfu/g and an arithmetic mean concentration of 2253 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 10 out of 50 samples having higher levels than 3 logs cfu/g)

# Performance of the sampling plans

c-value	$\sigma$	log geometric	Log arithmetic	Geometric (cfu/g)	Arithmetic (cfu/g)
20	0.8	3.1	3.8	1128	6155
15	0.8	2.9	3.6	706	3828
10	0.8	2.6	3.4	413	2253
20	1.2	3.1	4.7	1198	54,510
15	1.2	2.8	4.4	588	26,734
10	1.2	2.4	4.1	266	12,073

So over the years we get about a 0.5 log improvement, factor 3 in level

# A look from the actual situation in a country / slaughterhouse



European Food Safety Authority

EFSA Journal 2010; 8(03):1503

## SCIENTIFIC REPORT OF EFSA

### **Analysis of the baseline survey on the prevalence of *Campylobacter* in broiler batches and of *Campylobacter* and *Salmonella* on broiler carcasses in the EU, 2008<sup>1</sup>**

#### **Part A: *Campylobacter* and *Salmonella* prevalence estimates**

**European Food Safety Authority<sup>2, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

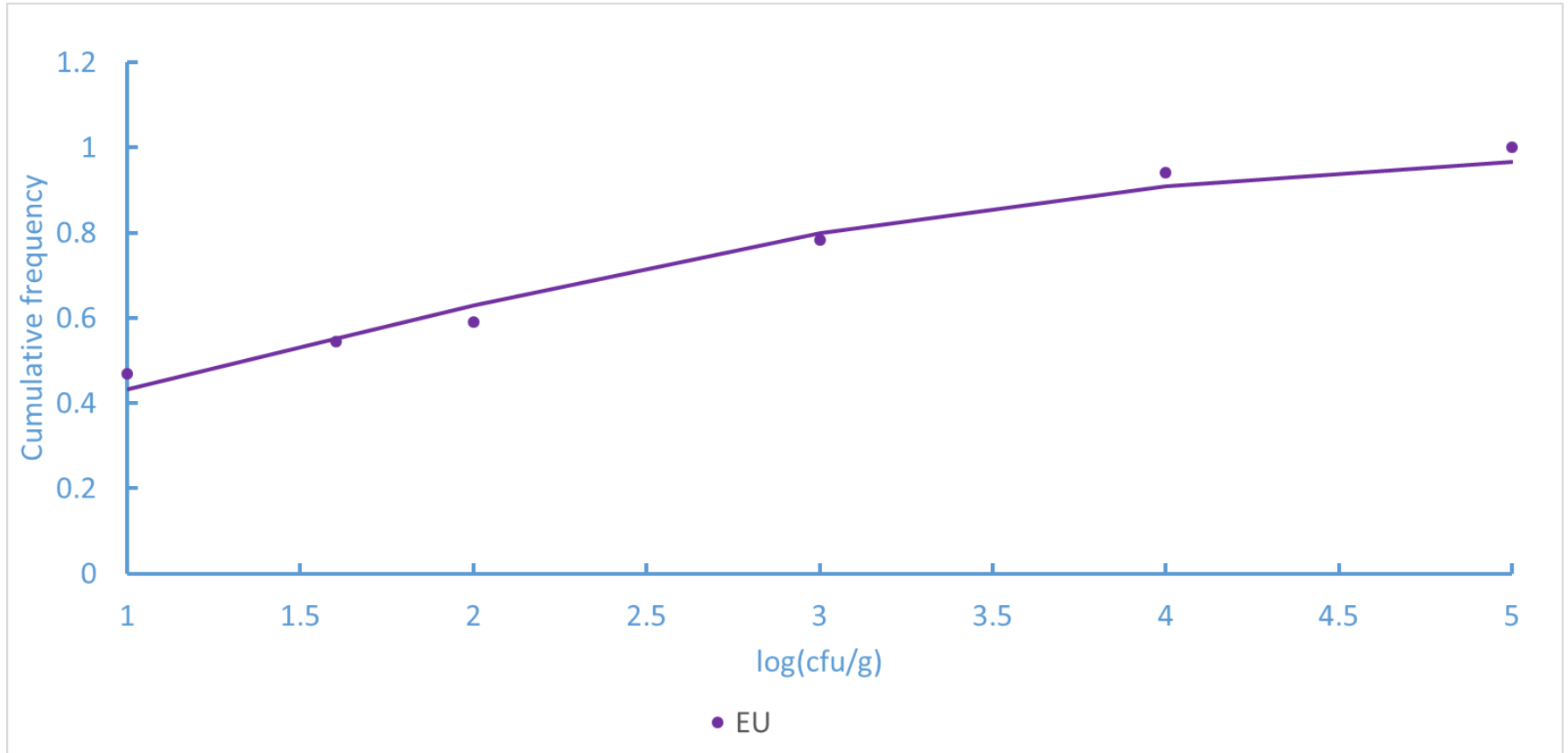
This scientific output, published 16 September 2011, replaces the earlier version published on 7 March 2011<sup>4</sup>.

Table 5. Categorical *Campylobacter* counts present on broiler carcasses, in the EU\*, 2008

Country	<i>Campylobacter</i> enumeration						Total
	<10 cfu/g	10-39 cfu/g	40-99 cfu/g	100-999 cfu/g	1,000-10,000 cfu/g	>10,000 cfu/g	
Austria	146 35.8	37 9.1	45 11.0	86 21.1	63 15.4	31 7.6	408 100
Belgium	188 49.5	20 5.3	19 5.0	74 19.5	66 17.4	13 3.4	380 100
Bulgaria	163 58.2	1 0.4	15 5.4	52 18.6	28 10.0	21 7.5	280 100
Cyprus	352 98.6	0 0	1 0.3	2 0.6	2 0.6	0 0	357 100
Czech Republic	205 48.6	4 1.0	8 1.9	92 21.8	78 18.5	35 8.3	422 100
Denmark	302 76.3	10 2.5	11 2.8	38 9.6	29 7.3	6 1.5	396 100
Estonia	100 98.0	0 0	1 1.0	0 0	1 1.0	0 0	102 100
Finland	361 97.8	4 1.1	2 0.5	1 0.3	1 0.3	0 0	369 100
France	102 24.2	54 12.8	47 11.1	154 36.5	54 12.8	11 2.6	422 100

cfu/g	<10	10-39	40-99	100-999	1000-10000	>10000	Total
EU	4320	685	436	1772	1453	534	9200

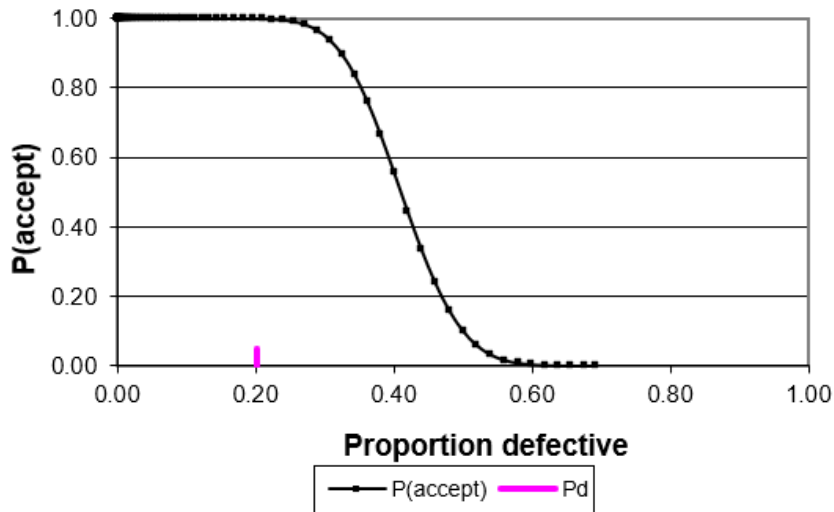
# Frequency distribution



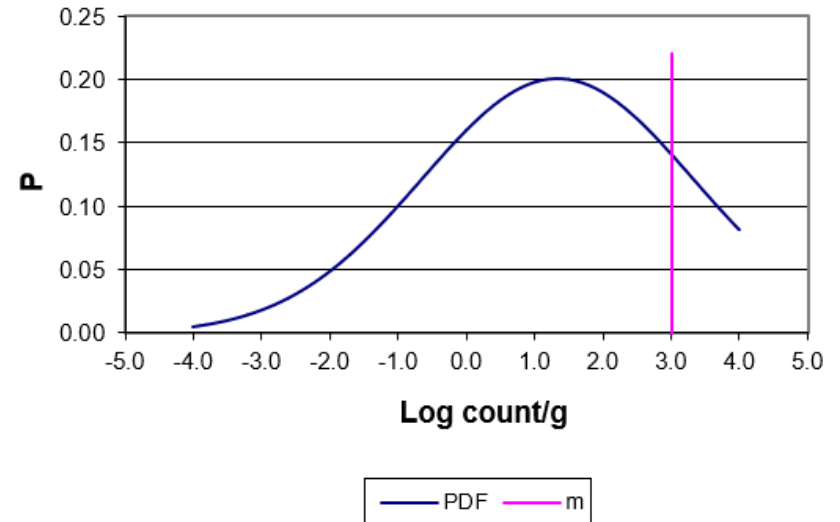
	mean	$\sigma$
EU	1.339	1.984

$$c=20, P_{\text{reject}}=0.04\%$$

Operating characteristic curve for proportion defective, with  $n=50$  and  $c=20$



Probability density function (PDF) for log counts. Distribution mean = 1.34 and sigma = 1.98



Lot acceptance for Pd		$P(\text{accept})$
Pd	10 %	100.0 %
actualPd	20.1 %	99.96 %

INPUTS		$P(\text{accept})$	
mean	1.34	Computed	99.96 %
sigma	1.98	Desired	5 %
m	3	Find mean that gives desired $P(\text{accept})$	
n	50	Find n that gives desired $P(\text{accept})$ or better (less)	
c	20	P(reject)	0.04 %

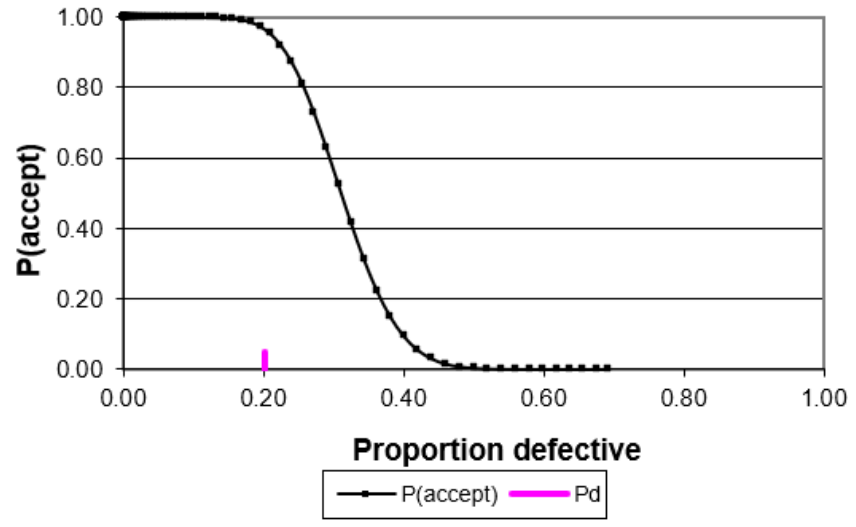
Sandbox: for your own calculations

FSO	3		
compliant %	0.798759	not comply	0.201241
	79.87592 %		20.12408 %

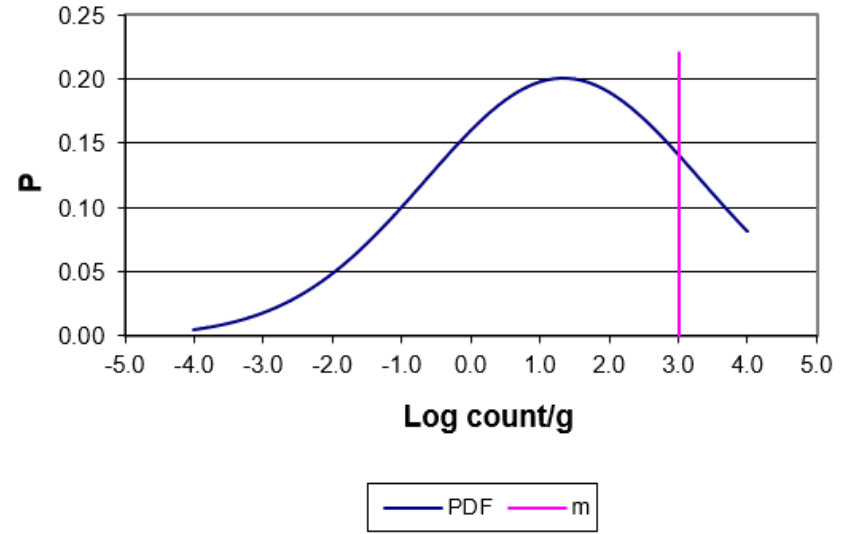
Means

$c=15, P_{\text{reject}}=3.3\%$

Operating characteristic curve for proportion defective, with  $n=50$  and  $c=15$



Probability density function (PDF) for log counts. Distribution mean = 1.34 and sigma = 1.98



Lot acceptance for Pd		$P(\text{accept})$
Pd	10 %	100.0 %
actualPd	20.1 %	96.75 %

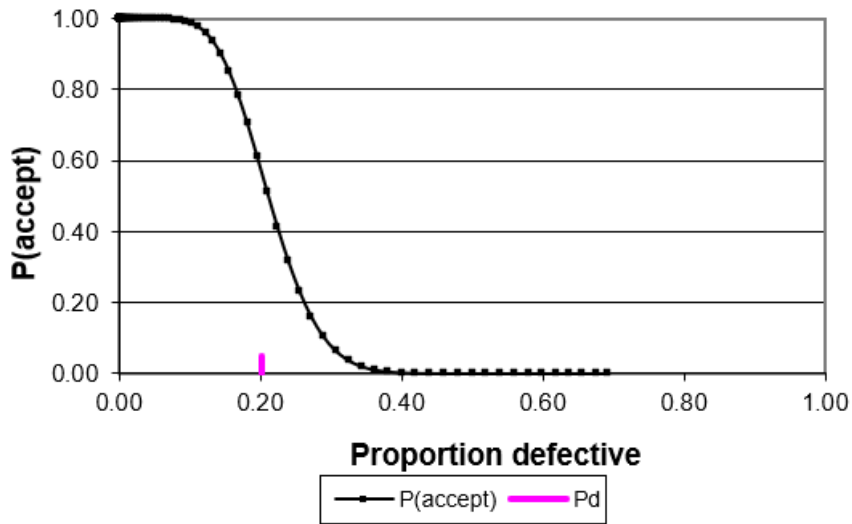
INPUTS		$P(\text{accept})$	
mean	1.34	Computed	96.75 %
sigma	1.98	Desired	5 %
m	3	Find mean that gives desired $P(\text{accept})$	
n	50	Find n that gives desired $P(\text{accept})$ or better (less)	
c	15	$P(\text{reject})$	3.25 %

Sandbox: for your own calculations			
FSO	3		
compliant	0.798759	not comply	0.201241
%	79.87592 %		20.12408 %

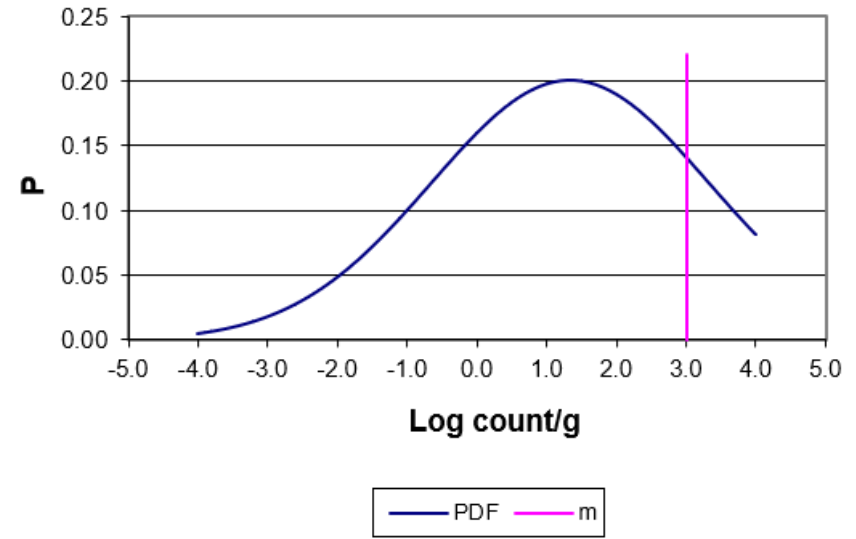


$c=10, P_{\text{reject}}=43\%$

Operating characteristic curve for proportion defective, with  $n=50$  and  $c=10$



Probability density function (PDF) for log counts. Distribution mean = 1.34 and sigma = 1.98



Lot acceptance for $P_d$		$P(\text{accept})$
$P_d$	10 %	99.1 %
actual $P_d$	20.1 %	57.49 %

INPUTS		$P(\text{accept})$	
mean	1.34	Computed	57.49 %
sigma	1.98	Desired	5 %
m	3	Find mean that gives desired $P(\text{accept})$	
n	50	Find n that gives desired $P(\text{accept})$ or better (less)	
c	10	$P(\text{reject})$	42.51 %

Sandbox: for your own calculations			
FSO	3		
compliant %	0.798759	not comply %	0.201241
	79.8759 %		20.1241 %



# Results ICMSF sheet

	mean log	$\sigma$	$P$ ( $>1000$ )	$c=20$	$c=15$	$c=10$
EU	1.3	2.0	0.20	0.00035	0.033	0.43

# Conclusions

The ICMSF tool can illustrate and calculate all kinds of effects of factors both graphically as well as numerically

