

Introduction of the ICMSF Sampling Plan Tool

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Food Safety Expert, The Netherlands

ICMSF Member 2001-present



Introduction

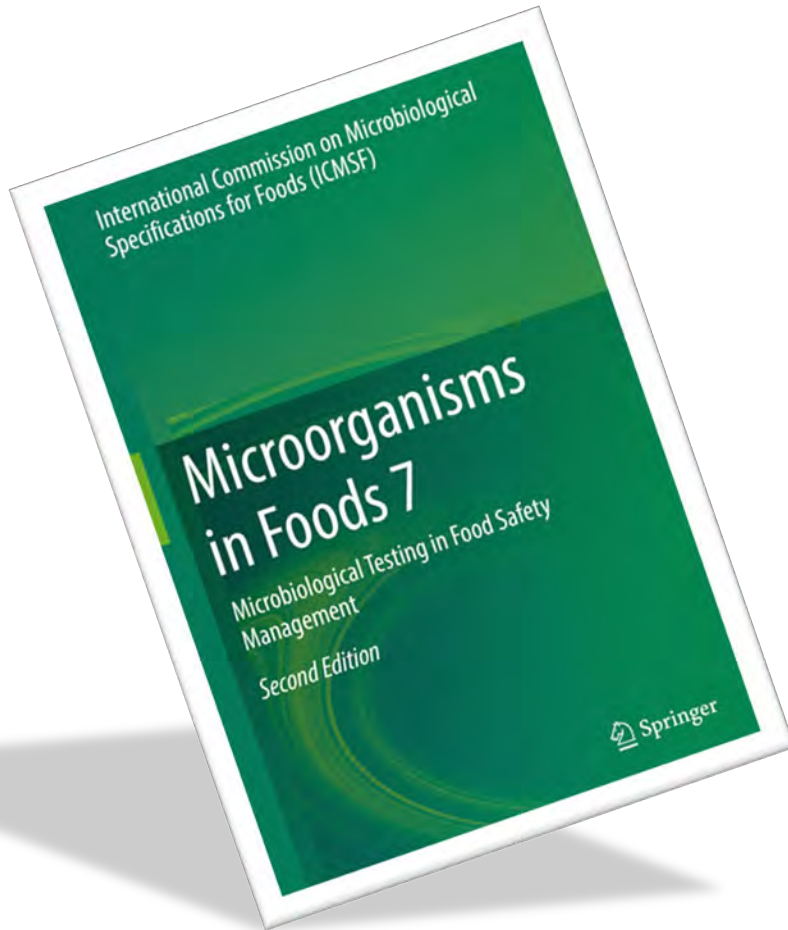
- Purpose of sampling and testing
- The ICMSF Sampling plan tool
- Where to find & download it
- Key design features
- Sampling plan dashboard example

Purpose of sampling and testing

- Microbiological testing is frequently used to verify process control and assess the acceptability of food lots
- Governments may establish acceptability criteria in the form of Microbiological Criteria (MCs) in food safety standards. Industry may use MCs in microbiological specifications for food lots.
- The original ICMSF concept defined 15 Cases of acceptability criteria¹, with specific sampling plans for MCs that are proportional to the necessary stringency of control
- MCs are statistically-based metrics that are often considered complex, challenging to understand and difficult to use

¹ ICMSF, 1986. Microorganisms in Foods 2. Sampling for Microbiological Analysis: Principles and Specific Applications, 2nd ed. University of Toronto Press, Toronto, Canada. ISBN: 0802056938

ICMSF Advice



Book 7: <http://www.springer.com/la/book/9783319684581>

Book 8: <https://link.springer.com/book/10.1007/978-1-4419-9374-8>

The ICMSF Sampling plan tool

- It is a Windows Excel Spreadsheet posted on ICMSF.org ¹
- The tool covers 2- and 3-class sampling plans that are either qualitative or quantitative
- The tool focuses on functionality and users need to understand the terminology and concepts underlying sampling plans
- It provides support to food professionals and others that, for instance, wish to understand sampling plan performance or design tailored sampling plans
- The tool is updated whenever there are relevant new scientific insights or functionalities. Peer-review is important to us.

¹ <https://www.icmsf.org/>

Where to find the tool?



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SOFTWARE DOWNLOADS

[Microbiological sampling plans](#) is a tool to explore ICMSF recommendations.

Standard Program

This spreadsheet calculates probabilities of acceptance for materials with different microbial loads and population standard deviations. The microbes are assumed to be lognormally distributed. This is new version 8 (November 2016) including additionally a tab with the effect of specificity and sensitivity.

[Download \(Spreadsheet 428 KB\)](#)

Control Measures Validation (FSO) Tool

A spreadsheet tool to explore the ICMSF Food Safety Objective (FSO) equation to determine the per cent compliance of products from processes that are affected by variability, and which is described in the publication "[Validation of control measures in a food chain using the FSO concept \(PDF 309KB\)](#)".

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Where to find the tool?

MICROBIOLOGICAL SAMPLING PLANS: A TOOL TO EXPLORE ICMSF RECOMMENDATIONS (SOME EXPLANATION)

TWO-CLASS SAMPLING PLANS (2-CLASS ENRICHMENTS AND 2-CLASS COUNTS)

THREE-CLASS SAMPLING PLANS (3CLASS)

Graphs for three-class sampling plans (from left to right):

Plot 1 – Operating characteristic (OC) surface showing probabilities of accepting a lot depending on two proportions: the proportion defective in the lot exceeding the microbiological limit M , named P_d , and the proportion marginally defective between the two microbiological limits m and M , named P_m .

Acceptance probabilities are calculated for given number of sampling units that are examined, n , given microbiological limits m and M , and given maximum number of sampling units that are allowed to be marginally defective, c , i.e. that are allowed to exceed the limit m but not M . The number of sampling units that are allowed to exceed M is assumed to be zero.

Plot 2 – Normal frequency distribution assumed for Log-transformed colony count numbers per gram to be found in sampling units drawn randomly from a lot characterized by given *mean* Log count per gram and given standard deviation *sigma*.

The red vertical line indicates the microbiological limit M specified in the sampling plan. Right to M the area under the curve corresponds to the proportion defective the lot contains, P_d . The pink vertical line indicates the microbiological limit m specified in the sampling plan. The area under the curve between m and M corresponds to the proportion marginally defective in the lot, P_m .

Plot 3 – Using these proportions defective, these proportions marginally defective, and the given sampling plan specifications for n and c corresponding probabilities of lot acceptance are calculated. Results are plotted (black) to show the OC curve in relation to Log arithmetic mean counts per gram.

Input fields for two-class sampling plans:

Yellow fields in the center –

- Lot characteristics: *mean* Log count per gram and standard deviation *sigma* shown in Plot 2.
- Sampling plan specifications: the microbiological limits, m and M , the number of sampling units, n , and the number of sampling units that are allowed to be marginally defective, c , i.e. that are allowed to exceed the limit m but not to exceed M .

Name Status Date modified

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- Share
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- Share
- Norton 360
- Open with...
- Zip and Share (WinZip Express)
- WinZip
- Scan with Malwarebytes
- Restore previous versions
- Send to
- Cut
- Copy
- Create shortcut
- Delete
- Rename

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Excel

Microsoft 365

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Key design features of the tool

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14	Nabisco Research			Wageningen University															
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17	East Hanover, NJ 07936-1944, USA			6700AA Wageningen						The file is further improved and updated.									
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Key design features of the tool



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7	microbial loads and population standard				workbook is accurate. In making this tool available to promote discussion													
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Key design features of the tool

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Version 2.03-2.0

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Version 2.07: O

Version 2.08: S



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DISCLAIMER ✕

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Key design features of the tool

Background reading

ICMSF book 2

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Relating microbiological criteria to food safety objectives and performance objectives

M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole, International Commission on Microbiological Specifications for Foods (ICMSF)

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About

Technical issues

Introduction

2-class enrichment

2-class counts

3-class counts

3-class mixed

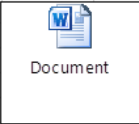
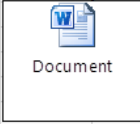
2-class enrich sensspec

TableSensSpec

Help and guidance

Different types of sampling plans

Key design features of the tool

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	This file can determine the performance of sampling plans for five cases:																		
2																			
3	● 2-class plans for enrichments (presence/absence, detection of the organism with no count results)											see tab 2-class enrichment							
4	● 2-class plans for quantitative determination (like concentration < 100 cfu/g)											see tab 2-class counts							
5	● 3-class plans for quantitative determination (where concentration is compared to both m and M)											see tab 3-class counts							
6	● 3-class mixed plans where m is qualitative and M is a concentration											see tab 3-class mixed							
7	● 2-class plans for enrichments including effects sensitivity and specificity											see tab 2-class enrich sensspec							
8	● Effects of sensitivity and specificity (fixed values) are also presented in a tabular form											see tab TableSensSpec							
9																			
10	Description of the used variables																		
11	Data entry cells are highlighted in yellow: All other cells are protected.																		
12																			
13	mean	mean of the (assumed) log normal distribution describing the occurrence of bacterial contaminants; unit is log cfu per gram																	
14	sigma	standard deviation of the same (assumed) log normal distribution																	
15	m	acceptable level of microbiological contamination, defined as an allowable concentration, or for enrichment no contamination in a sample of a certain weight, hence equals minus log(weight)																	
16	n	number of samples tested																	
17	c	number of samples whose contamination is allowed to exceed m (that is, test positive for contamination), yet the lot will be accepted																	
18	amount	sample weight, in gram (only relevant for 2-class enrichment plans)																	
19	P(accept)	the probability of accepting a specific lot; this is a function of the assumed contamination level (mean, sigma) and the sampling plan (n, c and amount). This is usually set at 5%, this then																	
20		means there is 5% probability of acceptance, or 95% probability of detecting such unacceptable lot																	
21	sensitivity	true positive rate = $TP / (TP + FN)$, (assumed to be fixed value depending on the method and not dependant on the concentration of the organisms)																	
22	specificity	true negative rate = $TN / (TN + FP)$, (assumed to be fixed value depending on the method and not dependant on the concentration of the organisms)																	
23																			
24	The Implied Acceptance Level, shown on all 'tabs' (worksheets), allows you to calculate the proportion of all the samples in the lot that would be expected to be above any chosen logCFU value																		
25	(i.e., a user input). For that logCFU, the z-score is also calculated.																		
26																			
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28	For a manual please open the following word-file									For an explanation on arithmetic and geometric means open the following word-file									
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Key design features of the tool

This file can determine the performance of sampling plans for five cases:

- 2-class plans for enrichments (presence/absence, detection of the organism with no count results) see tab 2-class enrichment
- 2-class plans for quantitative determination (like concentration)
- 3-class plans for quantitative determination (where concentration is divided into three classes)
- 3-class mixed plans where m is qualitative and M is a concentration
- 2-class plans for enrichments including effects sensitivity and specificity
- Effects of sensitivity and specificity (fixed values) are also included

Description of the used variables

Data entry cells are highlighted in yellow. All other cells are grey.

mean mean of the (assumed) log normal distribution describing the distribution of the organism in the lot

sigma standard deviation of the same (assumed) log normal distribution

m acceptable level of microbiological contamination (in log₁₀ cfu/g)

n number of samples tested

c number of samples whose contamination is allowed

amount sample weight, in gram (only relevant for 2-class enrichment)

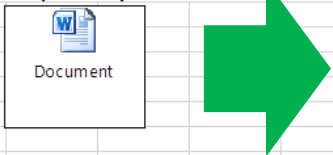
$P(\text{accept})$ the probability of accepting a specific lot; this is a function of the mean and sigma of the distribution, the standard deviation of the distribution, the sample weight, the number of samples tested, the number of samples permitted to test positive, and the acceptable level of microbiological contamination

sensitivity true positive rate= $TP/(TP+FN)$, (assumed to be fixed)

specificity true negative rate= $TN/(TN+FP)$, (assumed to be fixed)

The Implied Acceptance Level, shown on all 'tabs' (worksheets) (i.e., a user input). For that logCFU, the z-score is also calculated.

For a manual please open the following word-file



EXPLANATION OF THE SHEET

The **performance** of a sampling plan describes the lowest level of an organism that will be detected with a particular plan with a particular certainty. E.g. one can state that one wants to be 95% sure that a faulty lot is rejected. One has to make an assumption about the distribution of organisms in the samples, especially the standard deviation.

Example 1: Assessing the performance of a sampling plan with microbial counts.

To assess the performance of a sampling plan with $m=2 \log_{10}$ cfu/g and $n=10$ samples, for batches with a standard deviation σ of $0.8 \log_{10}$ cfu/g:

- Select the worksheet "2 class counts" (by clicking on the appropriate tab at the bottom of the workbook)
- Set cell J20, σ (the known or assumed standard deviation of counts in the lot), at $0.8 \log_{10}$ cfu/g
- Set J21 (m , the microbiological limit in \log_{10} cfu/g) at 2
- Set J22 (n , the number of samples to be tested) at 10
- Set J23 (c , the number of samples permitted to test positive) to 0
- Set M20 (the desired acceptance level) at 5%
- Press the button "Find mean that gives desired $P(\text{accept})$ ". Now cell J19 will change to 1.48, with cell M19 and M20 displaying 5%.

Interpretation of Example 1

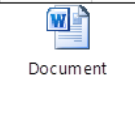
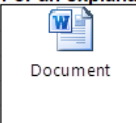

This can be interpreted as follows: a batch with a mean log concentration of more than $1.48 \log_{10}$ cfu/g and with a standard deviation σ of $0.8 \log_{10}$ cfu/g will be accepted with <5% probability, and hence rejected with >95% probability, if the microbiological limit m is 2 logs in each of $n=10$ samples.

Example 2: Assessing the performance of a sampling plan for an enrichment.

To assess the performance of a sampling plan with $m=\text{absence in } 25 \text{ g}$ and $n=10$ samples, for batches with a standard deviation (σ) of 0.8:

- Select the worksheet "2 class enrichment"
- Set cell J20 (σ , the standard deviation) at 0.8
- Set J22 (n , the number of samples) to 10
- Set J23 (c , the number of samples permitted to test positive) to 0

Key design features of the tool

	A	B	C	D	E	F	G	H	I	
1	This file can determine the performance of sampling plans for five cases:									
2	<ul style="list-style-type: none"> • 2-class plans for enrichments (presence/absence, detection of the organism with no count results) • 2-class plans for quantitative determination (like concentration < 100 cfu/g) • 3-class plans for quantitative determination (where concentration is compared to both m and M) • 3-class mixed plans where m is qualitative and M is a concentration • 2-class plans for enrichments including effects sensitivity and specificity • Effects of sensitivity and specificity (fixed values) are also presented in a tabular form 									
10	Description of the used variables									
11	Data entry cells are highlighted in yellow. All other cells are protected.									
13	mean	mean of the (assumed) log normal distribution describing the occurrence of bacterial counts								
14	sigma	standard deviation of the same (assumed) log normal distribution								
15	m	acceptable level of microbiological contamination, defined as an allowable concentration, or								
16	n	number of samples tested								
17	c	number of samples whose contamination is allowed to exceed m (that is, test positive for c								
18	amount	sample weight, in gram (only relevant for 2-class enrichment plans)								
19	P(accept)	the probability of accepting a specific lot; this is a function of the assumed contamination level								
20		means there is 5% probability of acceptance, or 95% probability of detecting such unacceptable								
21	sensitivity	true positive rate= TP/(TP+FN), (assumed to be fixed value depending on the method and								
22	specificity	true negative rate= TN/(TN+FP), (assumed to be fixed value depending on the method and								
24	The Implied Acceptance Level, shown on all 'tabs' (worksheets), allows you to calculate the proportion									
25	(i.e., a user input). For that logCFU, the z-score is also calculated.									
28	For a manual please open the following word-file					For an explanation on arithmetic a				
29										
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	About	Introduction			2-class enrichment	2-class counts	3-class counts	3-class m		

arithmetic mean of batch 2 is almost a factor 10 higher. This can also be seen in the log mean value of these batches. So the log mean gives a different result than the mean log. The geometric mean for both batches is 1000 cfu/g, resulting in the fact that the log(geometric mean) is equal to the mean log. This example illustrates the confusion when mixing log-transformed and actual numbers.

We can also invest...
Let's assume a batch of 0,6 log cfu/g. W which has the exp distribution of the a where there is a log arithmetic scale (re

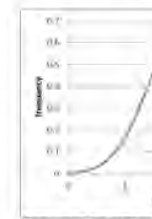


Figure 1, Panel A shows the distribution of log CFU. Panel B shows the distribution of the mean log. The mean log is 2,

mean log	s.d.
2	0,6

The log mean (log formula:

In the ICMSF samp 2class enrichment) both the mean va average log (geom while the log mea deviation) values increasing the stan health impact of su In the newest vers on the log arithme standard deviation)

A further explanab

FAO/WHO 2016. S Managers Guide. M

Microorganisms grow (or decline) exponentially over time, and levels in food can vary over many orders of magnitude. Therefore, microbial numbers are often expressed as their log-transformed values. This has an advantage that numbers are easier to understand: 7.4 log cfu is comprehended better than 25118864 cfu. Additionally, errors in determination of microbial counts are often relative to their numerical ("absolute") concentration due to the enumeration methods used, which usually involve serial dilutions. A log transformation makes the errors more consistent in scale across very large difference in absolute numbers. This also has advantages for data analyses because most currently used statistics are only appropriate if the data conform to a 'Normal' distribution. The best available data suggest that the logarithm of microbial counts/concentrations in foods are consistent with the Normal distribution. Accordingly, log transformation of numbers/concentrations of microorganisms in foods is often used and is usually effective and appropriate in describing, interpreting and analysing experimental results. This includes the design and interpretation of sampling plans that require that microorganisms in foods are "log-Normally" distributed (i.e. that the log cfu values are Normally distributed).

Conversely, the impact of organisms, including the public health risk from pathogens in foods, is most often related to the absolute number of organisms ingested. For example, at doses where probabilities of infection/illness are below 10% (i.e., below the ID10), most dose-response models for infection/illness predict that the probability of illness/infection is directly proportional to the dose ingested. Therefore, in the interpretation of the public health impact the absolute number of organisms is most relevant.

A consequence of the logarithmic transformation of data is that that the average of log transformed values differs from the average of the untransformed values. For example, the average contamination level of three samples with 100, 1000 and 10000 cfu/g present is 11100 cfu/g / 3 = 3700 cfu/g. The mean log contamination level is (2+3+4 log cfu)/3 = 3 log cfu/g. When converted to absolute numbers, this suggests a mean contamination level of only 1000 cfu/g. Importantly, in most situations, the risk from 3700 cfu/g is nearly four-fold higher than the risk from 1000 cfu/g.

As indicated above, it is the mean of the untransformed value that is most relevant to prediction of the effect of microbial loads. As such, while it is appropriate to calculate statistical summaries of microbial counts using log-transformed data (to facilitate the use of common statistical methods) it is the average of absolute values that is most relevant to estimation of risk.

Accordingly, it is important to specify clearly, and understand, the methods used in calculations and pay attention to the units used to express microbial loads, so that estimated risks can be compared without confusion.

As a second example, let's assume we have two groups of three products one with levels 100, 1000, and 10000 and one with 10, 1000, and 100000:

concentration in cfu/g							
	product 1	product 2	product 3	log mean	geometric mean	arithmetic mean	total number
batch 1	100	1000	10000	3.568202	1000	3700	11100
batch 2	10	1000	100000	4.527243	1000	33670	101010
concentration in log cfu/g							
	product 1	product 2	product 3	mean log			
batch 1	2	3	4	3			
batch 2	1	3	5	3			

If we consider these levels on log scale we can see that the log levels are for the first batch: 2, 3, and 4 log cfu/g and for the second batch: 1, 3 and 5 log cfu/g. Both batches have a mean log concentration of 3 log cfu/g. The second batch has higher variability, but based on the mean log concentration it has an equal level. If we now investigate these batches on arithmetic scale we see that the mean level is very different. The

Key design features of the tool

Types of sampling plans

2-class 2-class 3-class 3-class 2-class



About	Technical issues	Introduction	2-class enrichment	2-class counts	3-class counts	3-class mixed	2-class enrich sensspec	TableSensSpec
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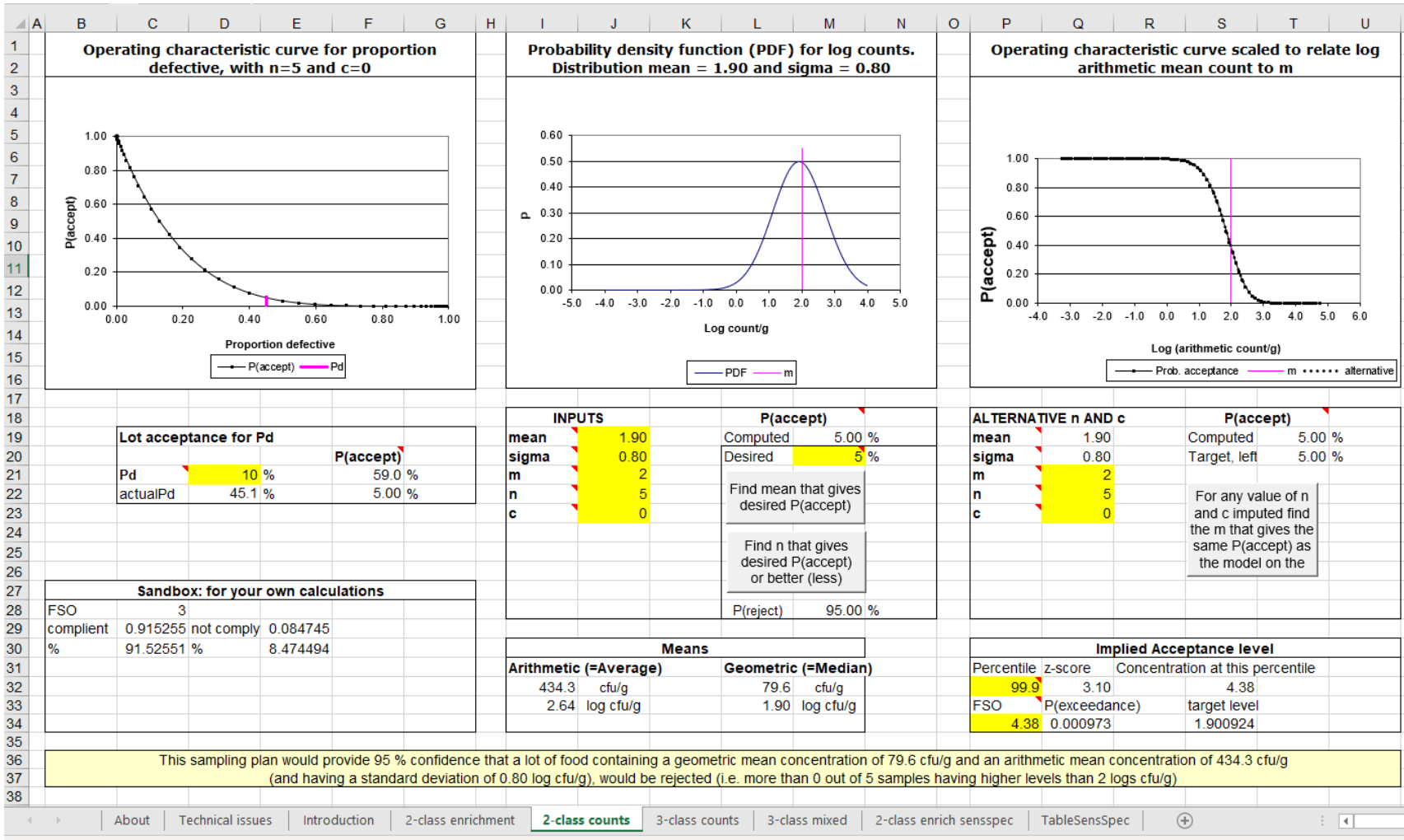
Qualitative

Quantitative

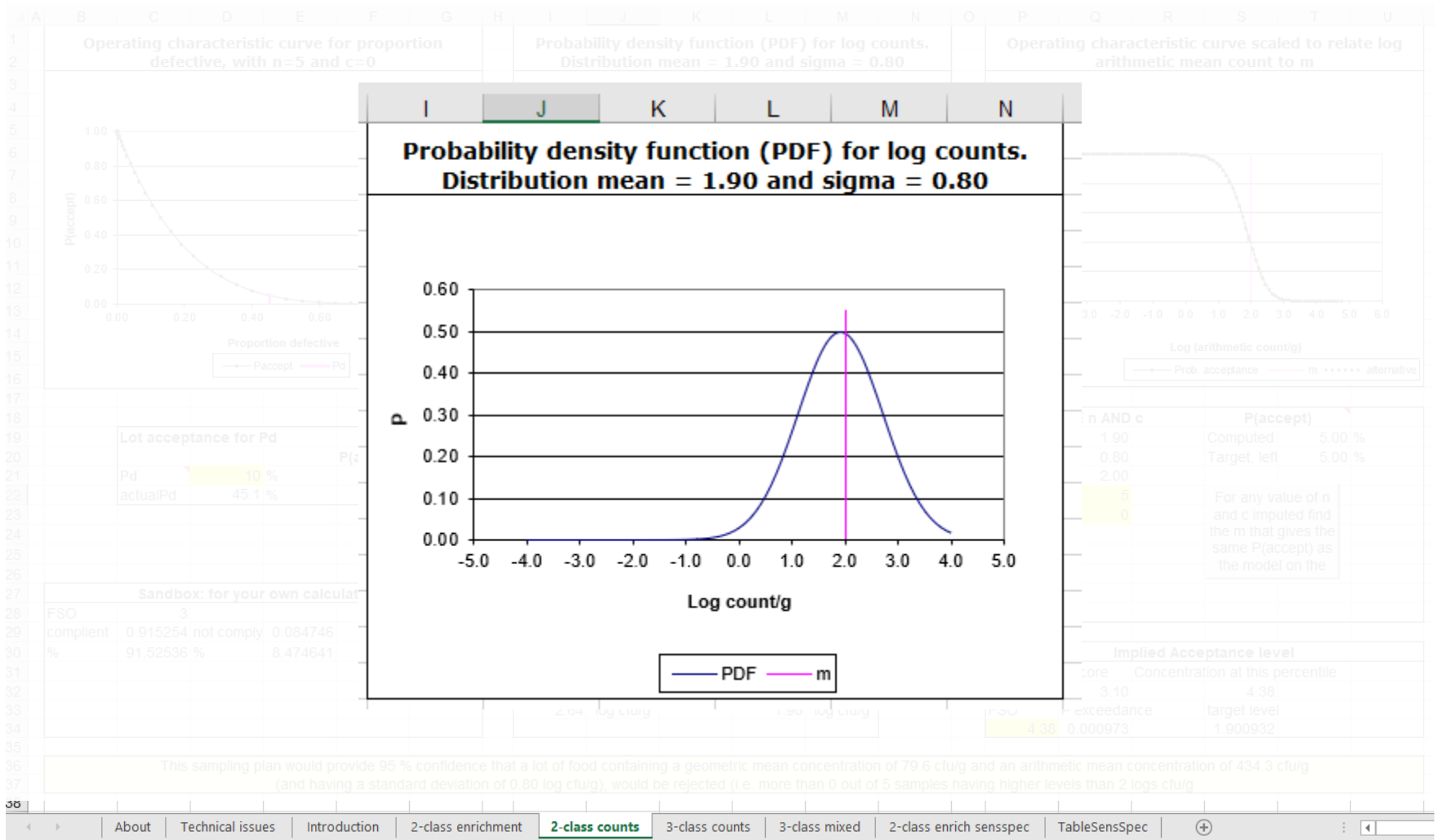
Qualitative



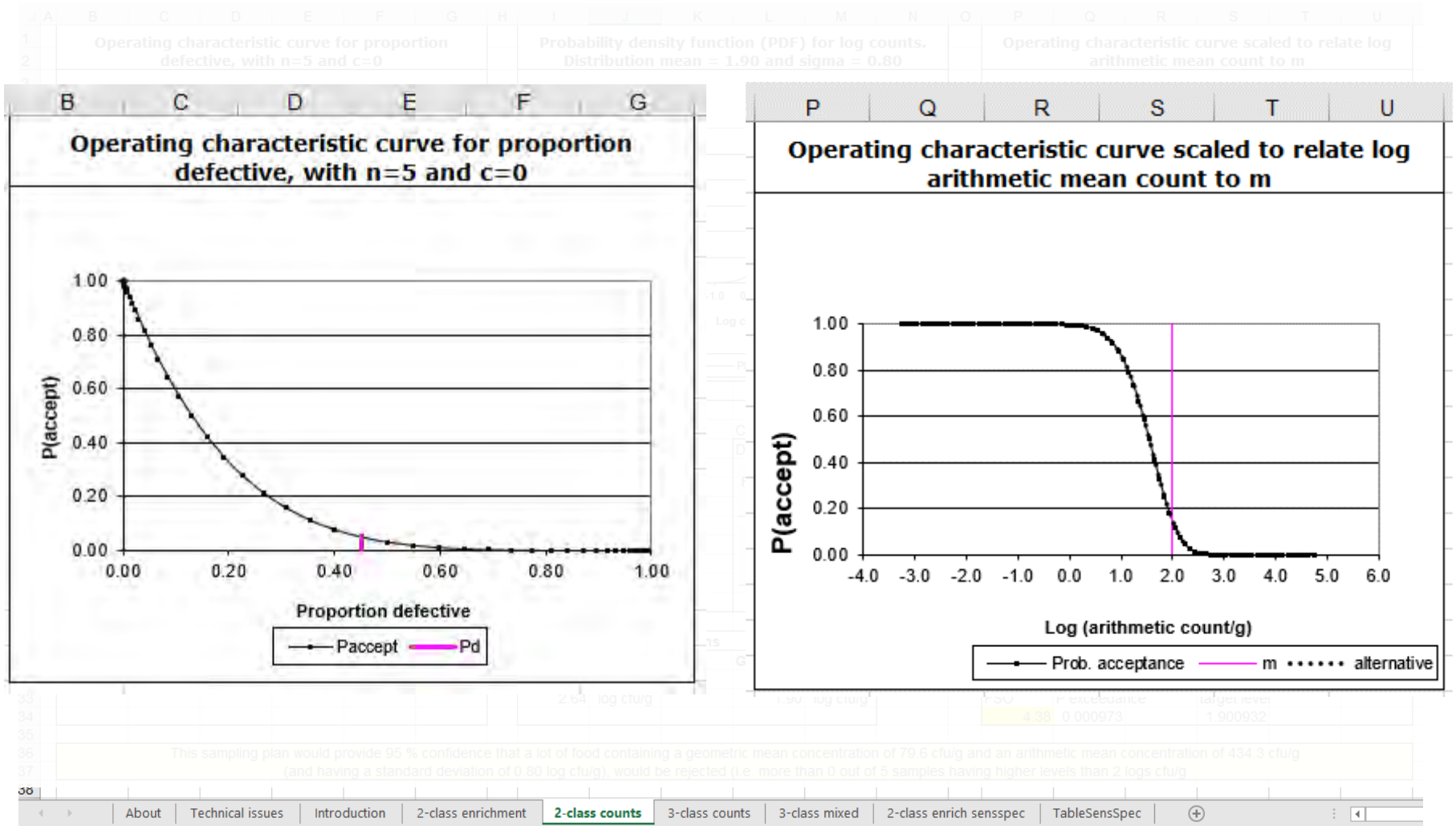
Example sampling plan dashboard



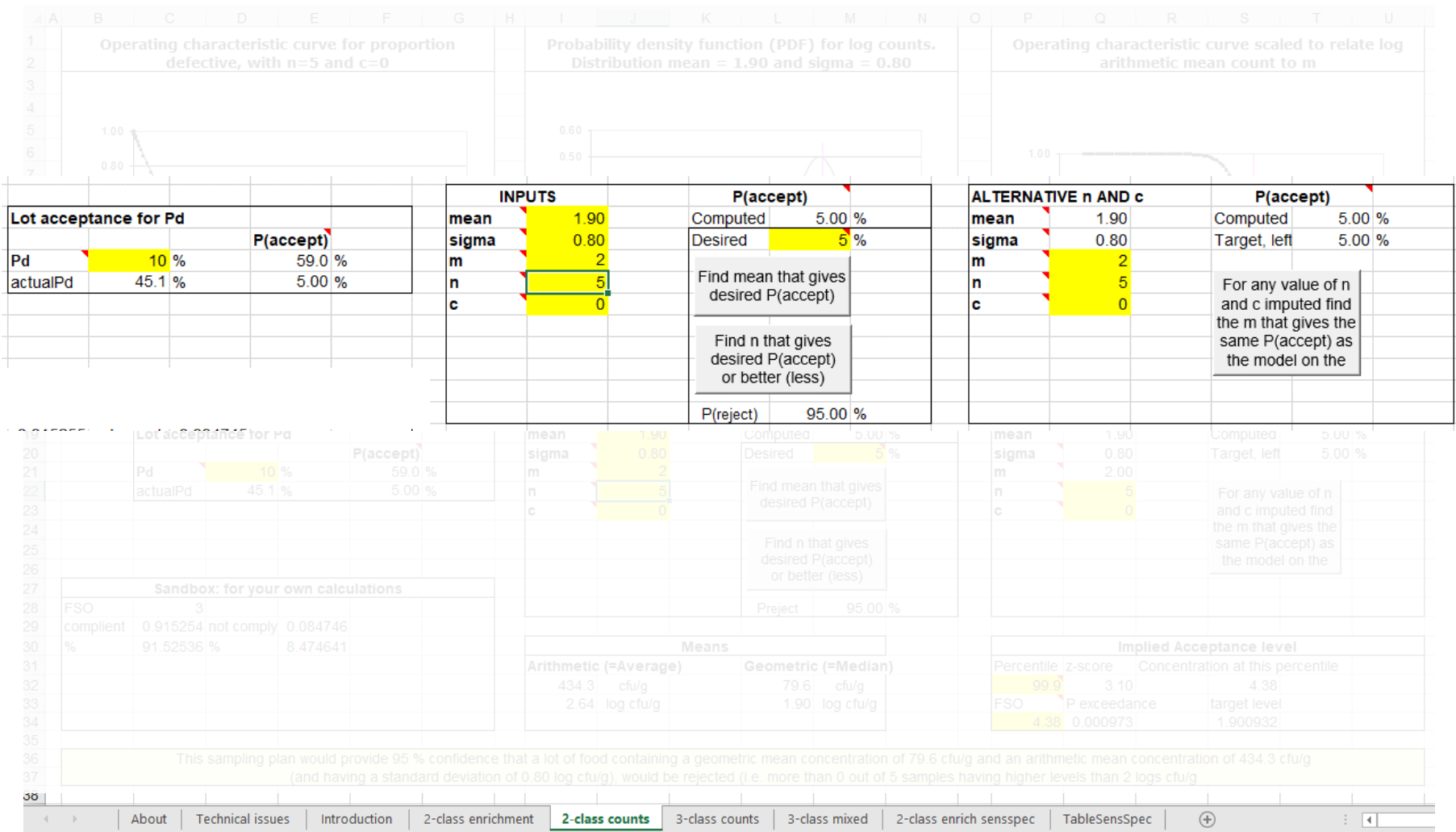
Example sampling plan dashboard



Example sampling plan dashboard



Example sampling plan dashboard



Example sampling plan dashboard

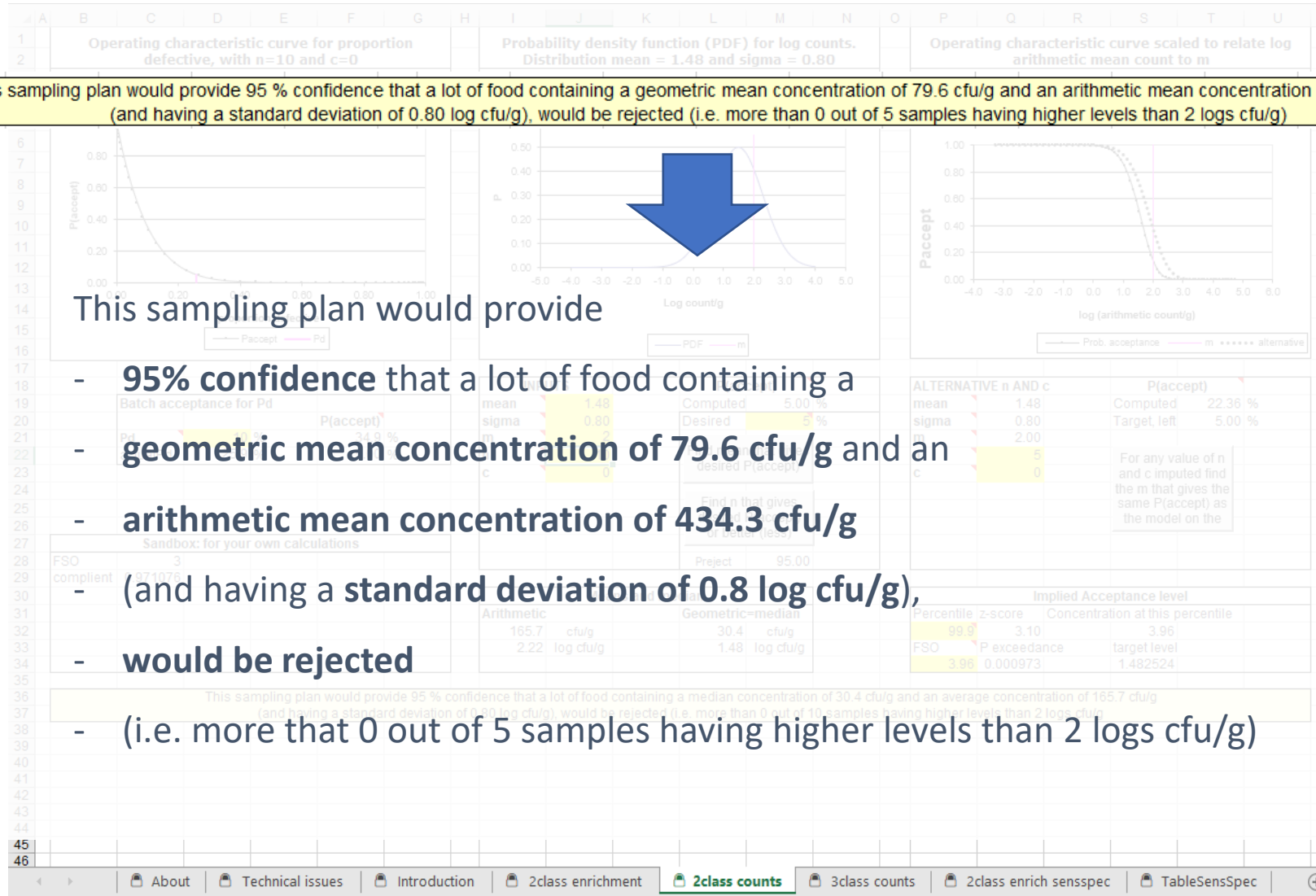
Lot acceptance for Pd				P(accept)		INPUTS		P(accept)		ALTERNATIVE n AND c		P(accept)			
Pd	10 %			Computed	59.0 %	mean	1.90	Computed	5.00 %	mean	1.90	Computed	5.00 %		
actualPd	45.1 %			Desired	5.00 %	sigma	0.80	Desired	5 %	sigma	0.80	Target, left	5.00 %		
				Find mean that gives desired P(accept)		m	2	Find n that gives desired P(accept) or better (less)		m	2	For any value of n and c imputed find the m that gives the same P(accept) as the model on the			
				P(reject)		n	5			n	5				
				95.00 %		c	0			c	0				
Sandbox: for your own calculations															
FSO	3														
compliant	0.915255	not comply	0.084745												
%	91.52551 %		8.474494												
				Means				Implied Acceptance level							
				Arithmetic (=Average)		Geometric (=Median)		Percentile		z-score		Concentration at this percentile			
				434.3	cfu/g	79.6	cfu/g	99.9	3.10	4.38					
				2.64	log cfu/g	1.90	log cfu/g	FSO	P(exceedance)	target level					
								4.38	0.000973	1.900924					
<p>This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 79.6 cfu/g and an arithmetic mean concentration of 434.3 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 0 out of 5 samples having higher levels than 2 logs cfu/g)</p>															

Example sampling plan dashboard

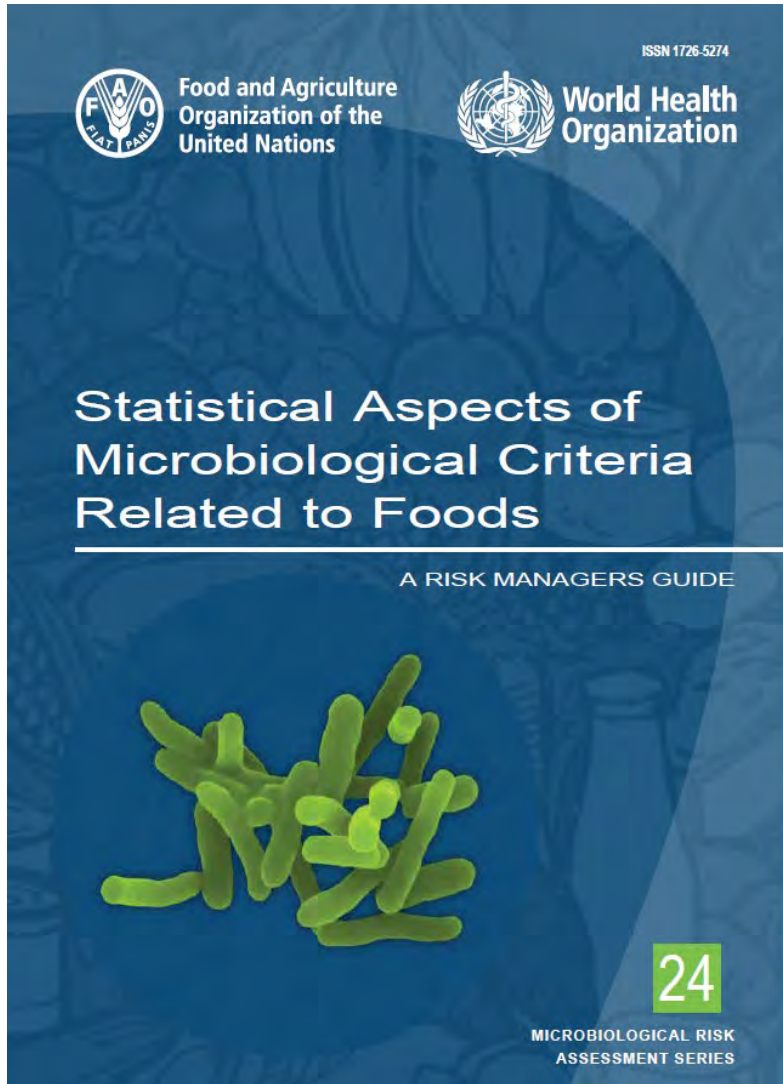
This sampling plan would provide 95 % confidence that a lot of food containing a geometric mean concentration of 79.6 cfu/g and an arithmetic mean concentration of 434.3 cfu/g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 0 out of 5 samples having higher levels than 2 logs cfu/g)

This sampling plan would provide

- 95% confidence that a lot of food containing a geometric mean concentration of 79.6 cfu/g and an arithmetic mean concentration of 434.3 cfu/g
- (and having a standard deviation of 0.8 log cfu/g),
- would be rejected
- (i.e. more than 0 out of 5 samples having higher levels than 2 logs cfu/g)



JEMRA Sampling plan resources



https://www.who.int/foodsafety/publications/mra_24/en/

Microbiological Criteria and Sampling Plan analysis tool

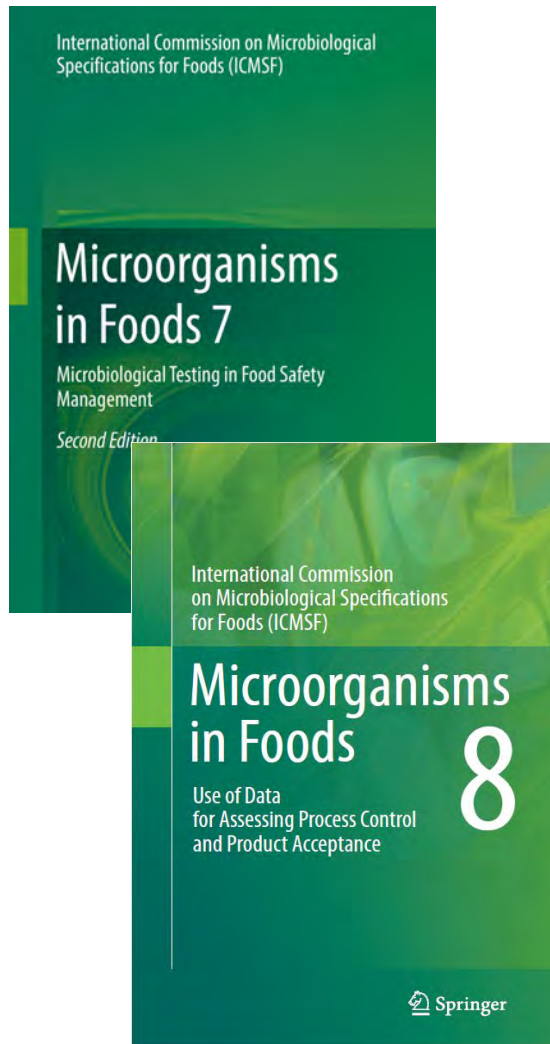
A Microsoft Excel version can be downloaded from: <http://fao.org/2/jABhk> and

<http://www.who.int/foodsafety/publications/mc-tool.xlsx>

Full playlist available at

https://www.youtube.com/playlist?list=PLzp5NgJ2-dK5pegu_aA0r0ITUfjM8Z7EI

Summary



- The ICMSF Sampling plan tool has been created to support users to interpret and establish Microbiological Criteria and sampling plans
- More information in Books 7 and 8
- Other video-clips in the ICMSF playlist present further context to the tool as well as details of its utility and functioning

For more information, see www.icmsf.org