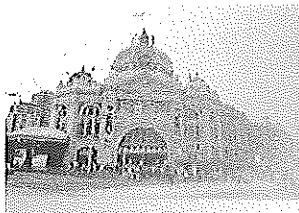

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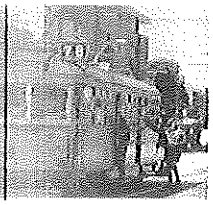

Workshop on:

Microbiological Sampling and Testing in Food Safety Management

"Securing Global Food Safety"

Sebel Albert Park Hotel, Melbourne, Australia
September, 2011

The Australian Institute of Food Science and Technology Incorporated

International Commission on Microbiological Specifications for Foods (ICMSF)

International Association for Food Protection

International Commission on
Microbiological Specifications for Foods

Examples and interpretation of the ICMSF sampling plan tool

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Overview

- Anatomy of the Workbook
- Simple Examples
- Assessing/verifying microbiological criteria
- Independent exploration of the spreadsheet

Tasmania

TIAR is a joint venture of the University of Tasmania and the Tasmanian Government

UTAS

Worksheets

- 'About'
- 'Technical Issues'
- 'Introduction'
- '2class enrichment'
- '2class counts'
- '3class counts'

'About'

- brief description of function
- sets out version history
- credits
- additional reading

'Technical Issues'

- essentially the same as the pre-workshop notes issued to you
- note corrections (follow up emails)
  - Point 10 actually relates to "2class counts" spreadsheet

'Introduction'

- explanation of the data entry cells in the spreadsheet
- links to "EXPLANATION OF THE SHEET" file (included in handouts)
- all data entry cells are highlighted in yellow
- the "sandbox"

Data inputs

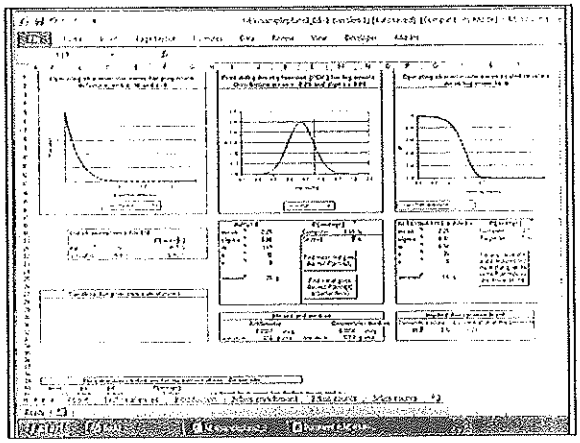
- mean — *mean of the (assumed) log normal distribution of bacterial contamination; unit is* log(cfu.g^{-1})
- sigma — *standard deviation (assumed) of the same log normal distribution*
- m — *tolerable level of microbiological contamination, defined as an allowable concentration or, for enrichment, no contamination in a sample of a certain weight, hence equals minus log(weight)*
- n — *number of samples tested*
- c — *maximum permissable number of samples in which the contamination is exceeds m (that is, test positive for contamination), but for which the lot will remain*
- amount — *sample weight, in grams*
- $P_{(accept)}$ — *the probability of accepting a specific lot; a function of the assumed contamination level* (mean, sigma) *and the sampling plan* (n, c *and* amount)

using the calculation sheets

- most users will only need to see and work with:
  - rows 1 – 33
  - columns A – U
- other cells contain intermediate calculated values, or reference values

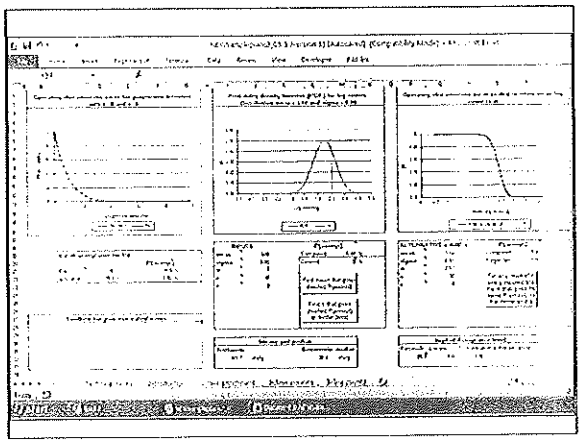
"2class enrichment"

- relevant for quantitative analysis of "presence/absence" testing, where a single test is either acceptable ("pass") or is not ("fail")
- implements the philosophy/statistical considerations described earlier - see also:
  - M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole and International Commission on Microbiological Specifications for Foods (ICMSF). (2009). *Food Control*, 20: 967-979
- *m* is defined by "amount" (i.e., the mass/volume of the enriched sample)



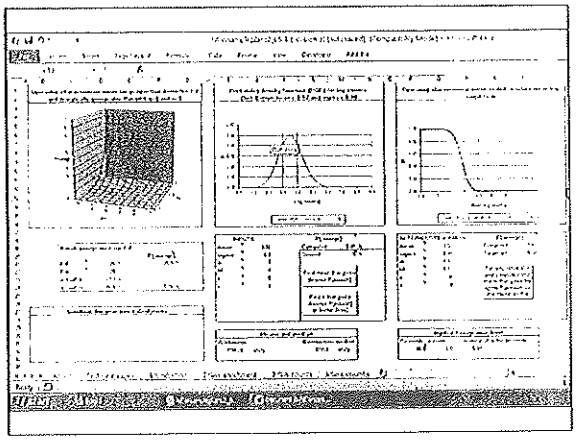
"2class counts"

- relevant for quantitative analysis of testing where the criterion is *explicitly* a numerical limit (e.g., 100 cfu.g^{-1})
- implements the philosophy/statistical considerations described earlier - see also:
  - M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole, International Commission on Microbiological Specifications for Foods (ICMSF). (2009). *Food Control*, 20: 967-979
- main difference is that *m* is no longer defined by the sample size but is "user specified".



"3class counts"

- relevant for quantitative analysis of testing where there are two criteria ("marginally acceptable" and "unacceptable" and each is defined by a numerical limit (e.g., 100 cfu.g^{-1}, 1000 cfu.g^{-1})
- Implements the philosophy/statistical considerations described earlier - see also:
  - M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole, International Commission on Microbiological Specifications for Foods (ICMSF). (2009). *Food Control*, 20, 967-979
- *m* and M are not defined by the sample size but are "user specified".



Exercises 1

- refer to the pages "Explanation of the Sheet" and follow through the exercises outlined there.

Exercises 2

- for the actual examples on the following slides calculate the test sensitivity from the sampling plan proposed and other information provided
- we will compare to "official" values

Criteria for powdered infant formula

These are to be applied to the finished product (powder from) at factory after primary packaging or anytime thereafter up to the point when the primary package is opened

Microorganisms	n	c	m	Class Plan
Enterobacter sakazakii (Cronobacter species)	30	0	0/10 g	2
Salmonella [1]	60	0	0/25 g	2

Where n = number of samples that must conform to the criteria; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality.

For *E. sakazakii* calculate the mean concentration if:

i) the standard deviation (sigma) is 0.8 and you achieve 95% confidence of detection of an unacceptable lot;
ii) the standard deviation (sigma) is 0.5 and you achieve 95% confidence of detection of an unacceptable lot

For Salmonellae calculate the mean concentration if:

iii) the standard deviation (sigma) is 0.8 and you achieve 95% confidence of detection of an unacceptable lot;.

Criteria for process hygiene

These are to be applied to the finished product (powder from) or at any other previous point that provides the information necessary for the purpose of the verification

The safe production of these products is dependent on maintaining a high level of hygiene control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these tests are not needed to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs

Microorganism	n	c	m	M	Class Plan
Mesophilic Aerobic Bacteria	5	2	500 g	5000 g	3
Enterobacteriaceae [2]	10	2 [2]	0/10 g	Not applicable	2

For *Enterobacteriaceae* calculate the mean concentration if:

i) the standard deviation (sigma) is 0.8 and you achieve 95% confidence of detection of an unacceptable lot;
ii) the standard deviation (sigma) is 0.5 and you achieve 95% confidence of detection of an unacceptable lot

Microbiological criteria for ready-to eat foods in which growth of *L. monocytogenes* can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or post of entry (for imported products) to the point of sale	*Listeria monocytogenes*	5[a]	0	Absence in 25 g (< 0.04 cfu/g)[b]	2[c]

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed

[b] Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140)

For *Listeria monocytogenes* calculate the mean concentration if:

i) the standard deviation (sigma) is 0.25 and you achieve 95% confidence of detection of an unacceptable lot

Microbiological criterion for ready-to eat foods in which growth of *L. monocytogenes* will not occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or post of entry (for imported products) to the point of sale	*Listeria monocytogenes*	5[a]	0	100 cfu/g[b]	2[c]

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed

[b] This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140)

For *L. monocytogenes* calculate the mean concentration if:

i) the standard deviation (sigma) is 0.25 and you achieve 95% confidence of detection of an unacceptable lot

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Questions and Discussion

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