Using risk assessments to set performance objectives and performance criteria that achieve a food safety objective

ICMSF / RAC / ILSI / IAFP / IFT Symposium
on Relating Microbiological Testing and
Microbiological Criteria to Public Health Goals

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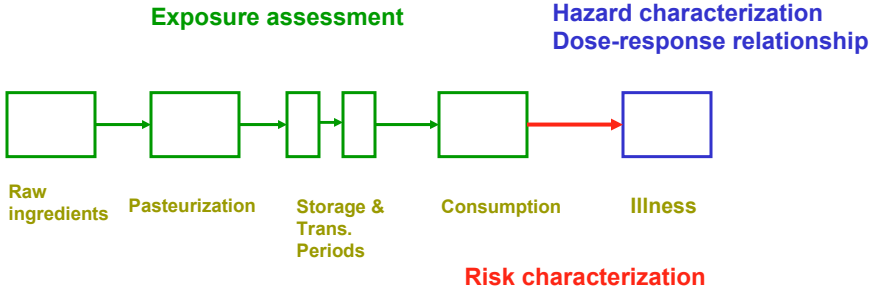
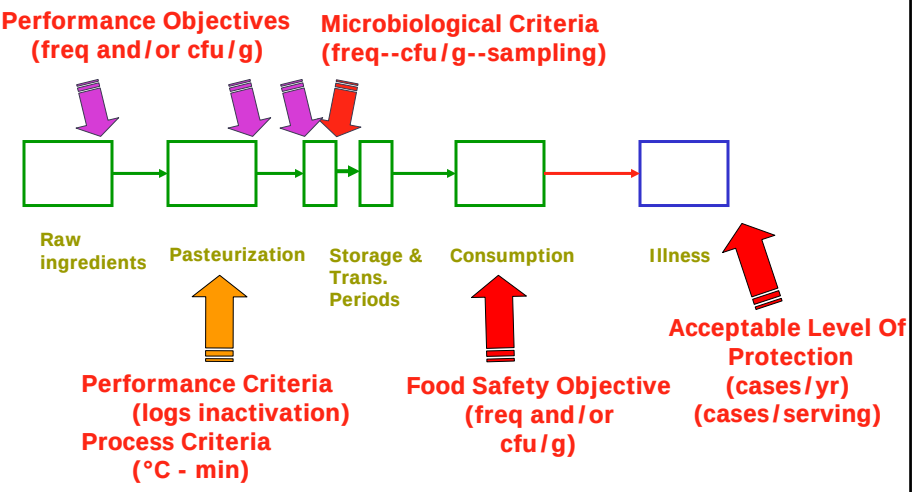
Note: This presentation represents the author's views and not necessarily FDA policy.

Process Risk Assessment



Process Risk Assessment



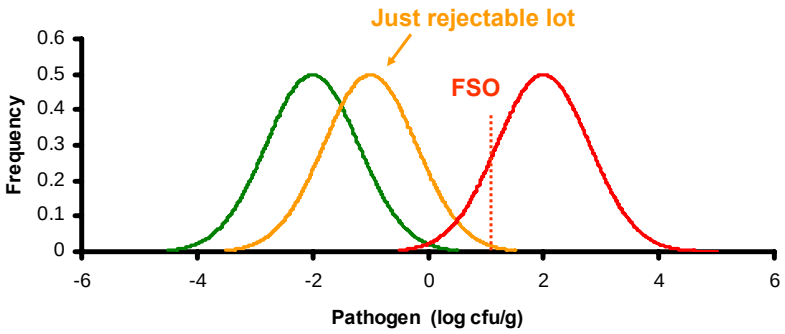
Hypothetical FSO paradigm for cut lettuce

$$H_0 + \sum R + \sum I < FSO$$

ALOP Log(illness/serving)	FSO Log(CFU/serving)	FSO Log(CFU/g)	PO / MC RETAIL Log(CFU/g)	PO / MC MANUFAC-TURING Log(CFU/g)	PO RAW LETTUCE Log(CFU/g)
- 4.0	6.0	4.3	2.3 / 1.3	1.3 / 0.3	1.2
- 5.0	5.0	3.3	1.3 / 0.3	0.3 / - 0.7	0.2
- 6.0	4.0	2.3	0.3 / - 0.7	- 0.7 / - 1.7	- 0.8
- 7.0	3.0	1.3	- 0.7 / - 1.7	- 1.7 / - 2.7	- 1.8
- 8.0	2.0	0.3	- 1.7 / - 2.7	- 2.7 / - 3.7	- 2.8
- 9.0	1.0	- 0.7	- 2.7 / - 3.7	- 3.7 / - 4.7	- 3.8

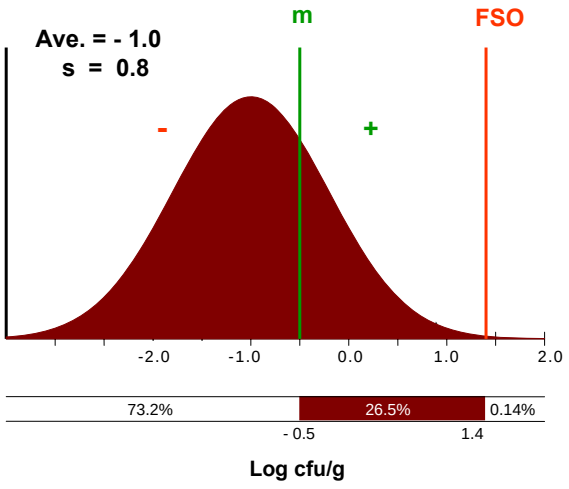
FSO and food process lots

Distributions of samples within a lot

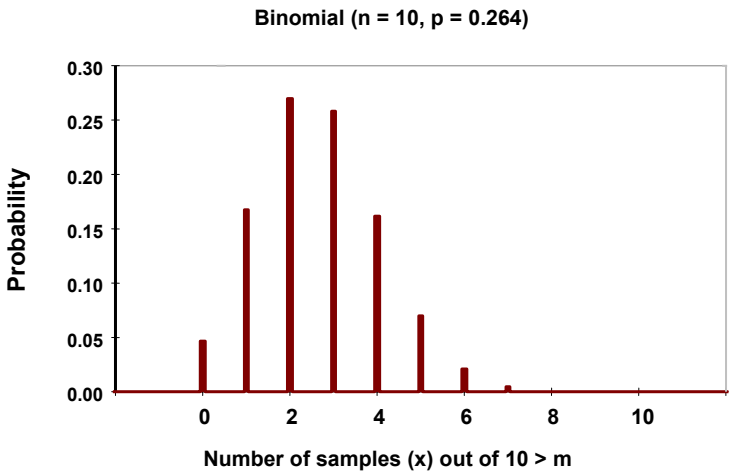


Lot mean + 3 std < FSO **≈ 0.14% > FSO**

Just rejectable lot



Using binomial distribution to determine number of samples

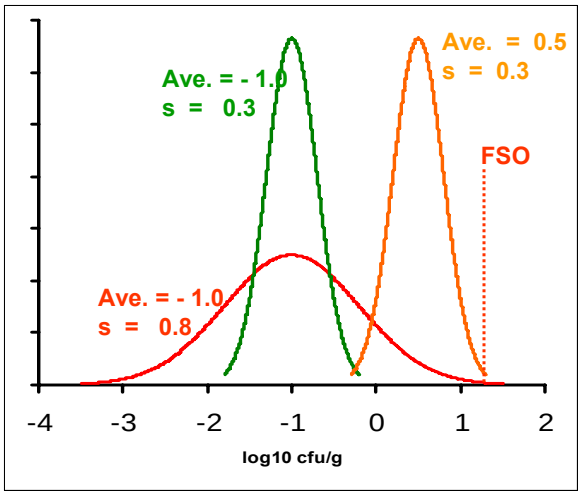


Microbiological Criteria

- Given a sampling, sample prep and analytical protocol:

  Ave. = - 1.0
  s = 0.8
  m = - 0.5 $\log_{10}$ cfu/g
  95% confidence in rejecting lot
  c = 0
  n = 10

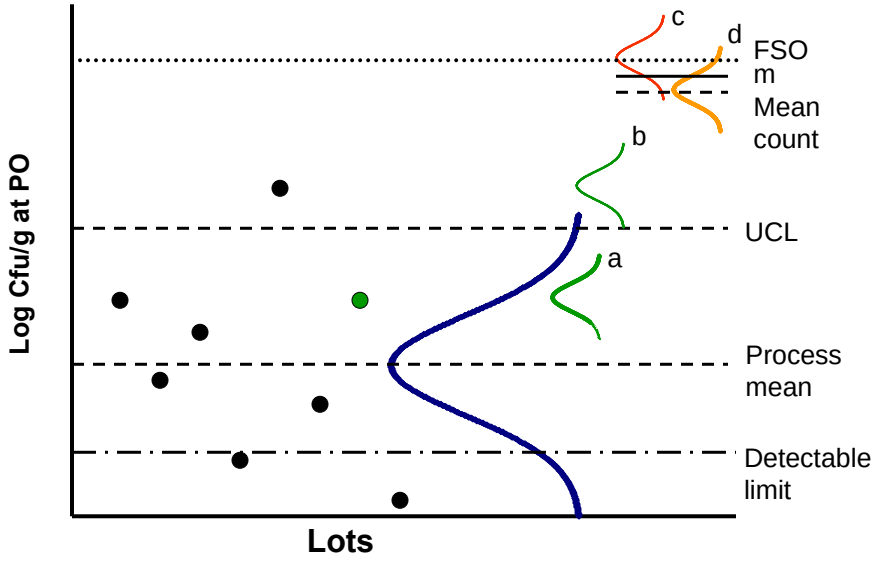
Same lot, different sampling protocol



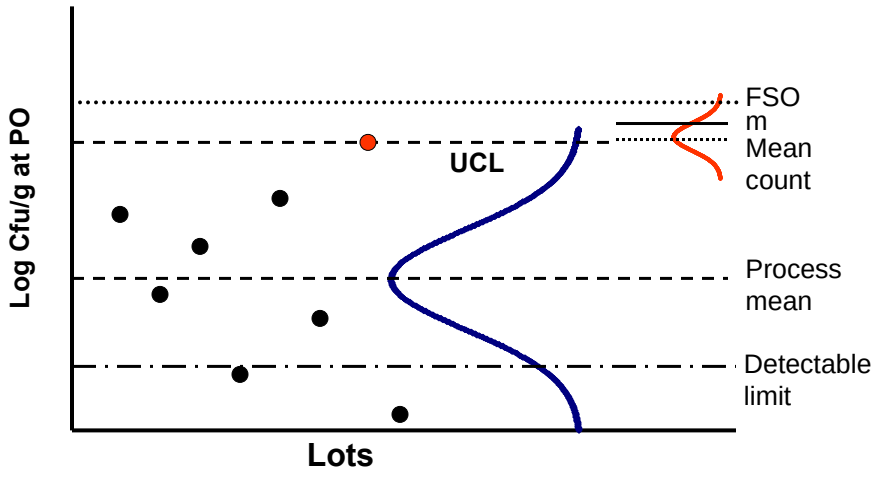
Steps in setting a MC

1. Determine the standard deviation of samples within lots of the food
   Given sampling & analytical protocol
   Adjust test sensitivity so 15-40% of samples are positive
2. Determine number of samples to reach desired confidence of detecting at least 1 positive
   c = 0
3. If not satisfactory, adjust sampling and analytical protocol to reduce within lot variation and repeat

Process control chart with FSO and MC



Process control chart with lowest FSO and MC



Process mean, UCL, PO, FSO and MC relationship

- **Sample (serving) < process mean + 3 process standard deviations + 3 within lot standard deviations ≤ FSO/PO**
- **The UCL = process mean + 3 process standard deviations**
- **The FSO > UCL + 3 within lot standard deviations**

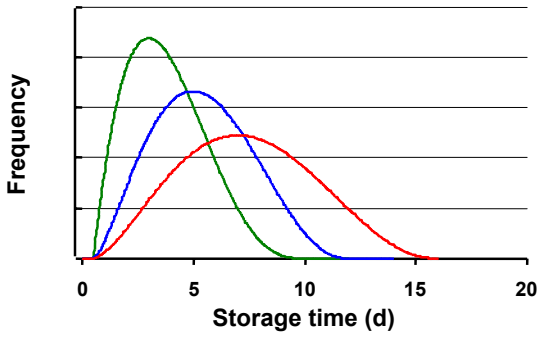
Two dimensional process risk assessments

- Variation—real differences in parameter values
- Uncertainty—lack of knowledge about the true value of the parameter
  - Lack of quality studies
  - Less relevant studies
  - Poor methodology
- Enter parameter values and calculate RA
  - cfu/serving < UCL/MC/PO/FSO?
  - Sensitivity analyses

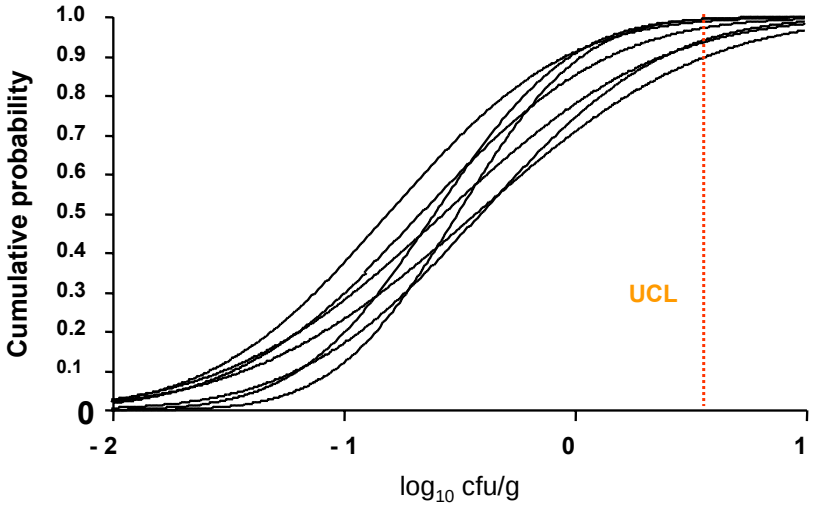
Data with variation and uncertainty

Storage time
Pert (min, most likely, max)

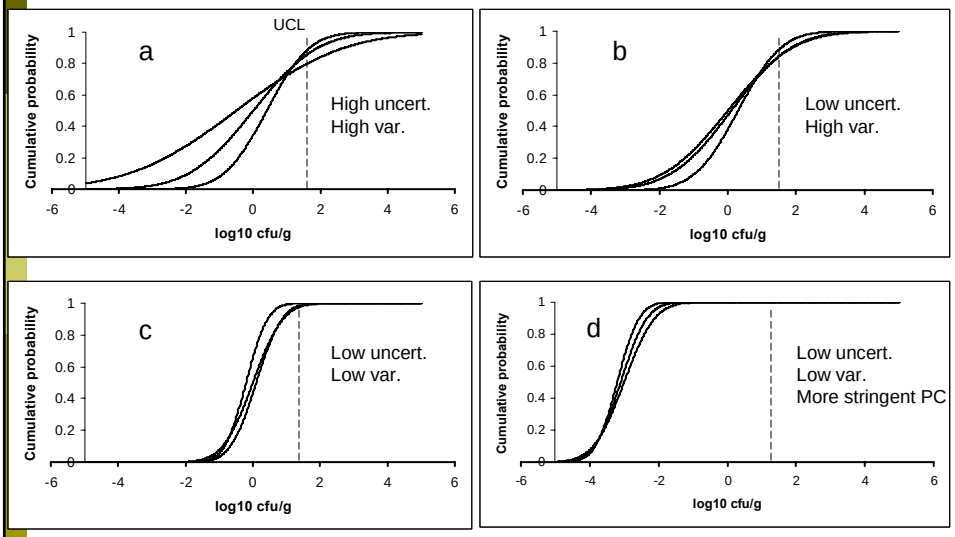
Pert(0.5, 5, 13)
Uncertainty most likely Uniform(3,7)
Uncertainty max Uniform(10, 16)



Cumulative output of 2D risk assessment at PO



Cycles of increased process control

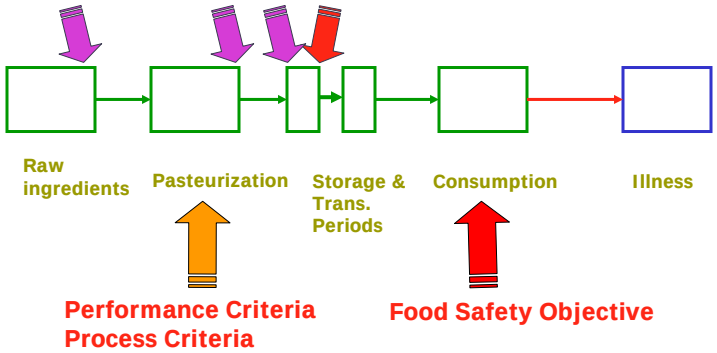


Designing a process to meet a FSO

1. Collect data and run 2-dimensional RA
2. If samples from lots (servings) fails FSO, use sensitivity analysis to determine parameter(s) contributing most to uncertainty, collect better data, rerun RA
3. If samples (servings) still fail FSO, use sensitivity analysis to determine parameter(s) contributing most to variation, reduce variation, update data, rerun RA
4. If samples (servings) still fail FSO, change process (POs or PCs) to reduce entire distribution to meet FSO
5. Collect new data, rerun RA and validate process meets FSO, verify continued compliance

Process Risk Assessment

Performance Objectives Microbiological Criteria



Performance Criteria
Process Criteria

Food Safety Objective