

(Evaluation of Control Banding through) Statistical Analysis of Exposure Monitoring Data

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Donald Rumsfeld on probability:

As we know, there are known knowns; there are things we know we know.

We also know there are known unknowns; that is to say, we know there are some things we do not know.

But there are also unknown unknowns – the ones we don't know we don't know.

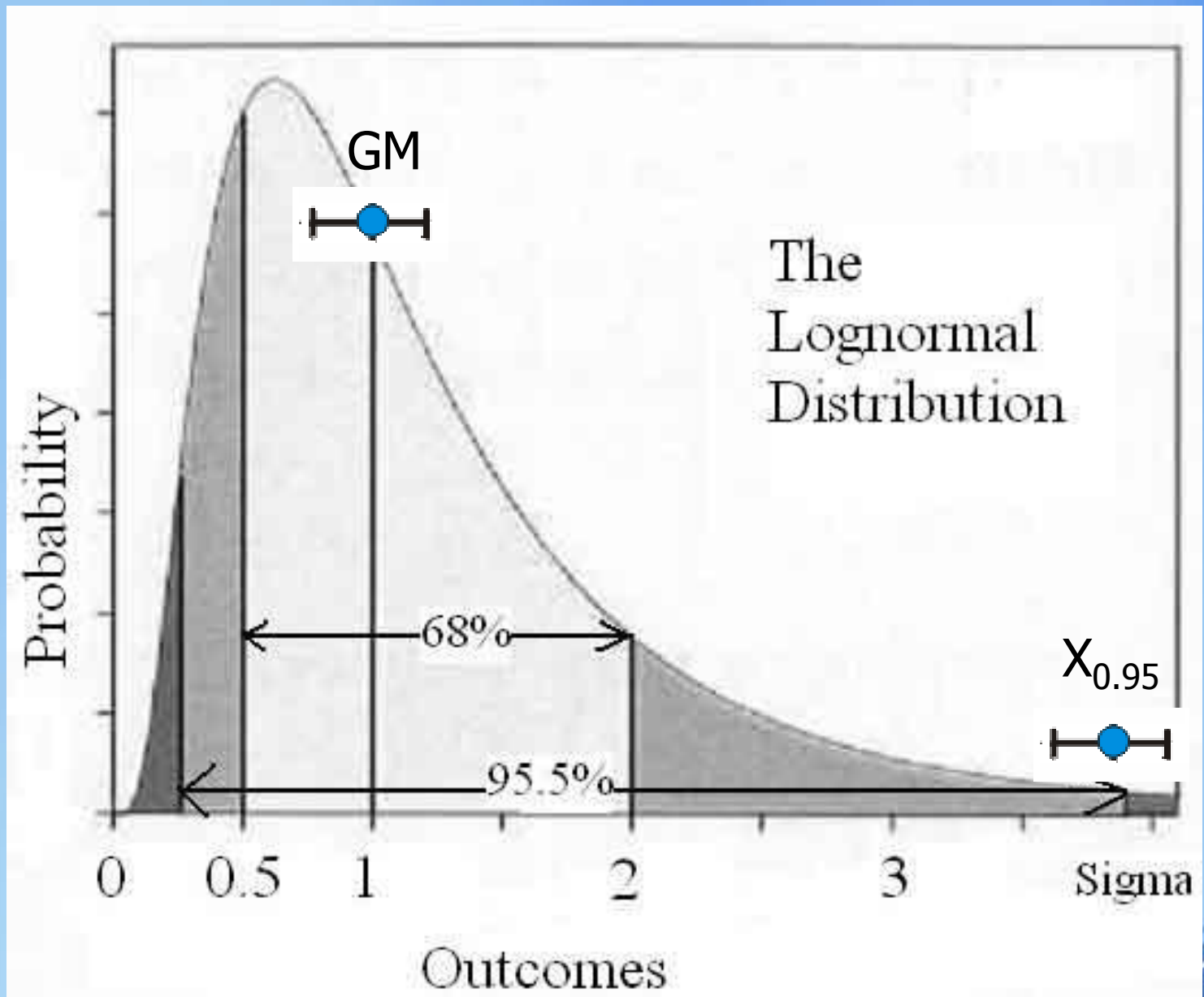
Hypotheses

- Expert judgment and therefore expert systems, such as control bands, are not good at precise estimates.
- However, they are good within an order of magnitude – and depending on the context, that is often sufficient
- Acceptance criteria also depends on context
- Bayesian statistics may be very useful in assessing control banding systems – but realistic estimates on which to base prior probabilities are critical

Statistical Terms - Review

- Arithmetic (μ or \bar{x}) v. Geometric Mean (GM)
- 95th Percentile ($X_{0.95}$)
- Confidence interval (CI)
 - Upper Confidence Limit (UCL)

Conventional Statistics – GM, $X_{0.95}$, UCL

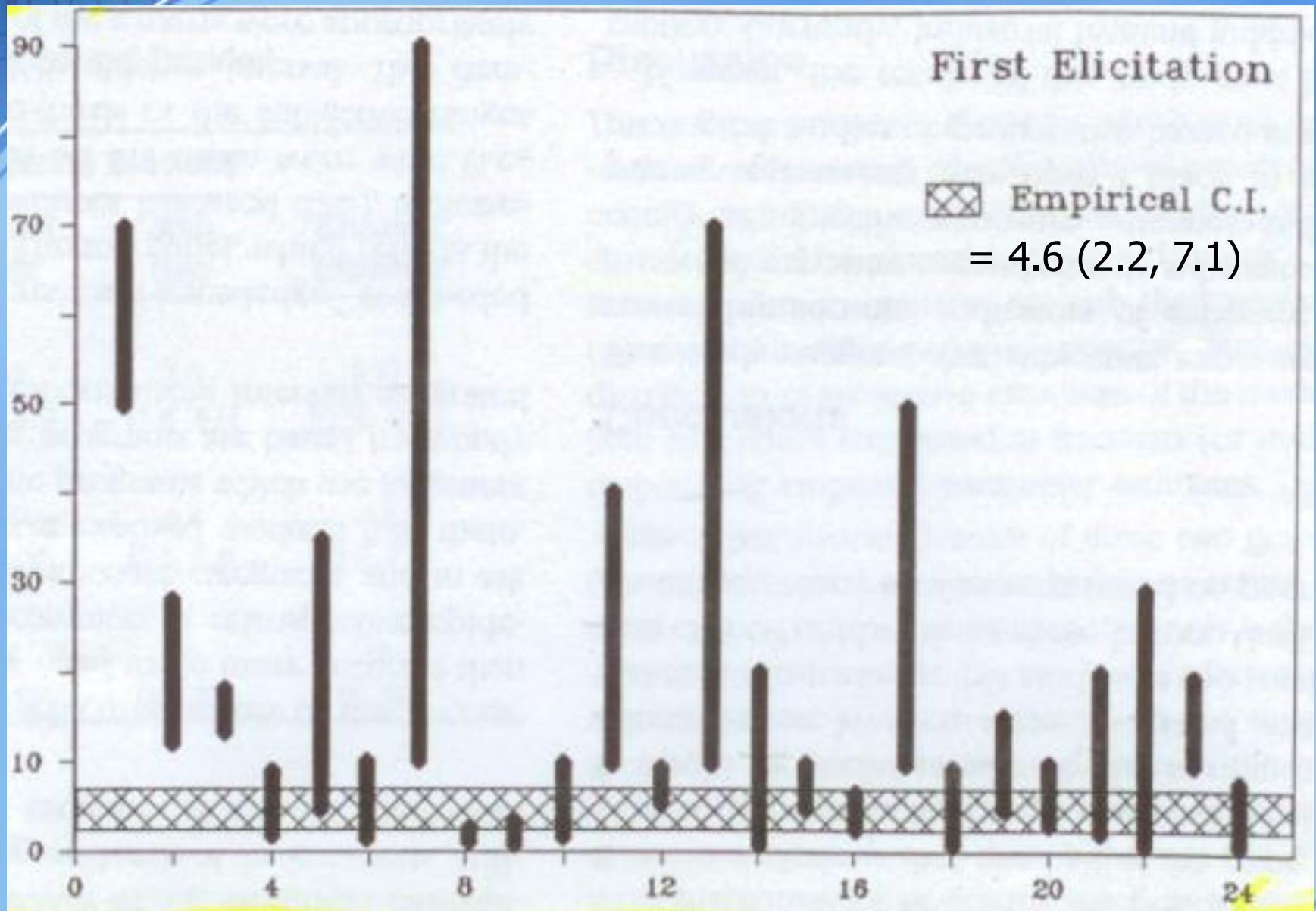


Typical Statistical Assumptions

- Homogeneous data set
- Random data
- Normal / lognormal data

Accuracy and Precision of Experts: Importance of Context

- Expert judgment and therefore expert systems, such as control bands, are not good at precise estimates.
- However, they are good within an order of magnitude – and depending on the context, that is often sufficient



Source: Hawkins and Evans, *Appl. Ind. Hyg.* 4: 61-68, 1989

AIHA Exposure Ratings

Rating*	Description	Values
0	Trivial	< 0.01 x OEL
1	Highly controlled	0.01 to 0.1 x OEL
2	Well controlled	0.1 to 0.5 x OEL
3	Controlled	0.5 to 1 x OEL
4	Poorly controlled	>1 x OEL

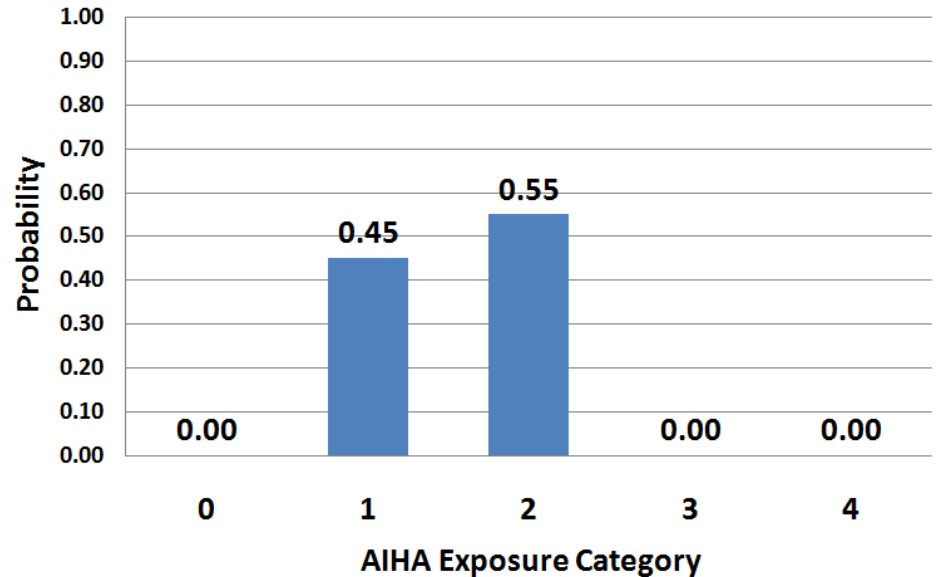
OEL = Occupational Exposure Limit

*Ratings based on “A Strategy for Assessing and Managing Occupational Exposures”, 2006, 3rd edition. American Industrial Hygiene Association, Fairfax, VA. (trivial category added)

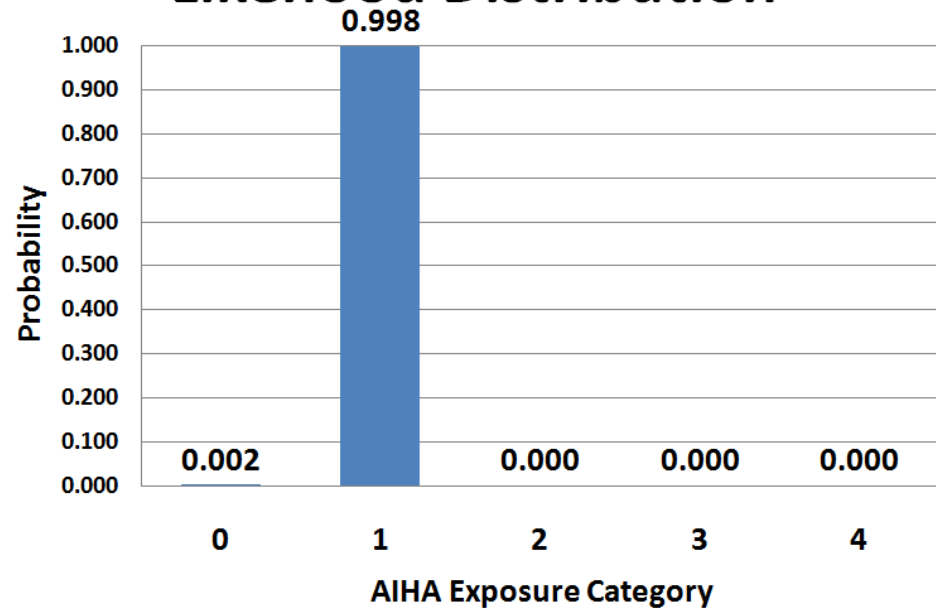
OEL = 100 ppm
(top and bottom 2 removed)

134 8-hr TWA measurements →

Prior Probability

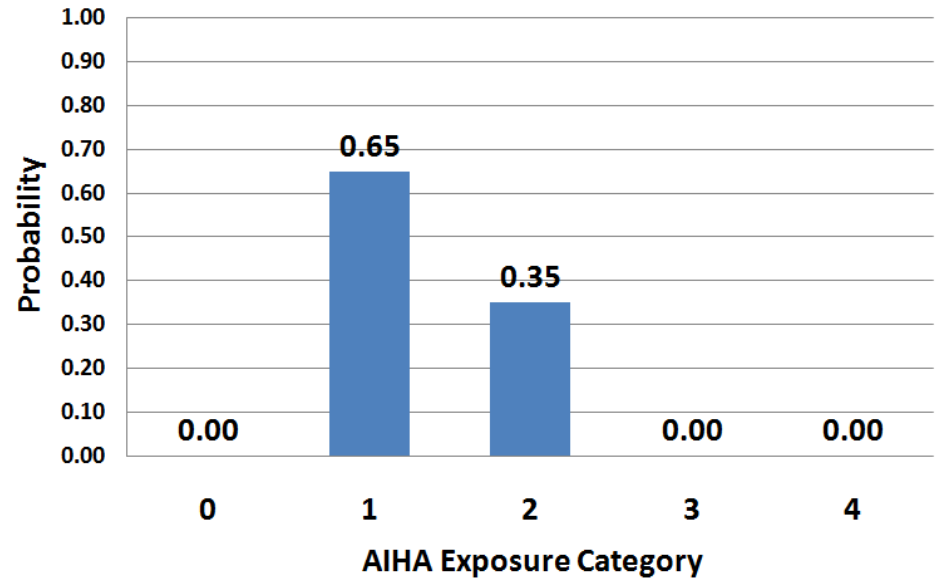


Likelihood Distribution

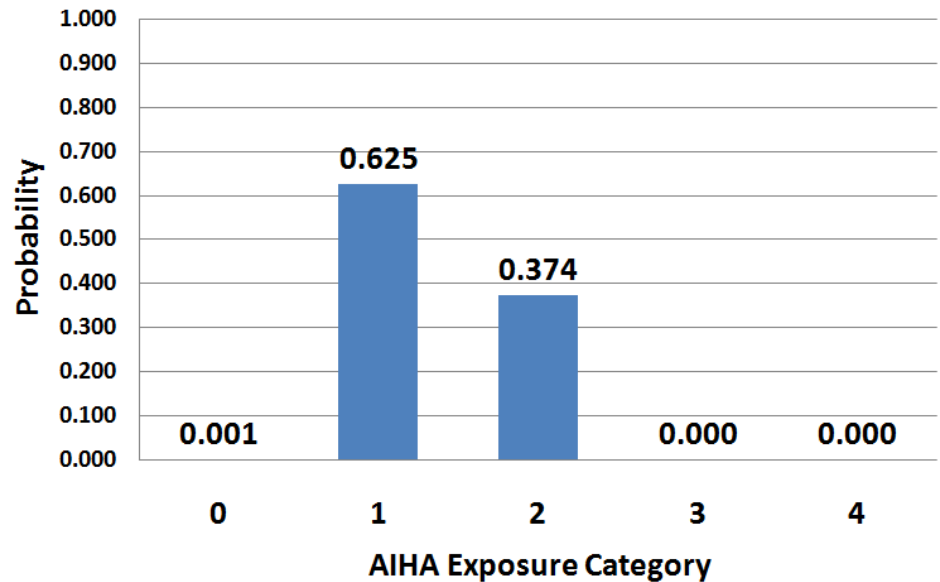


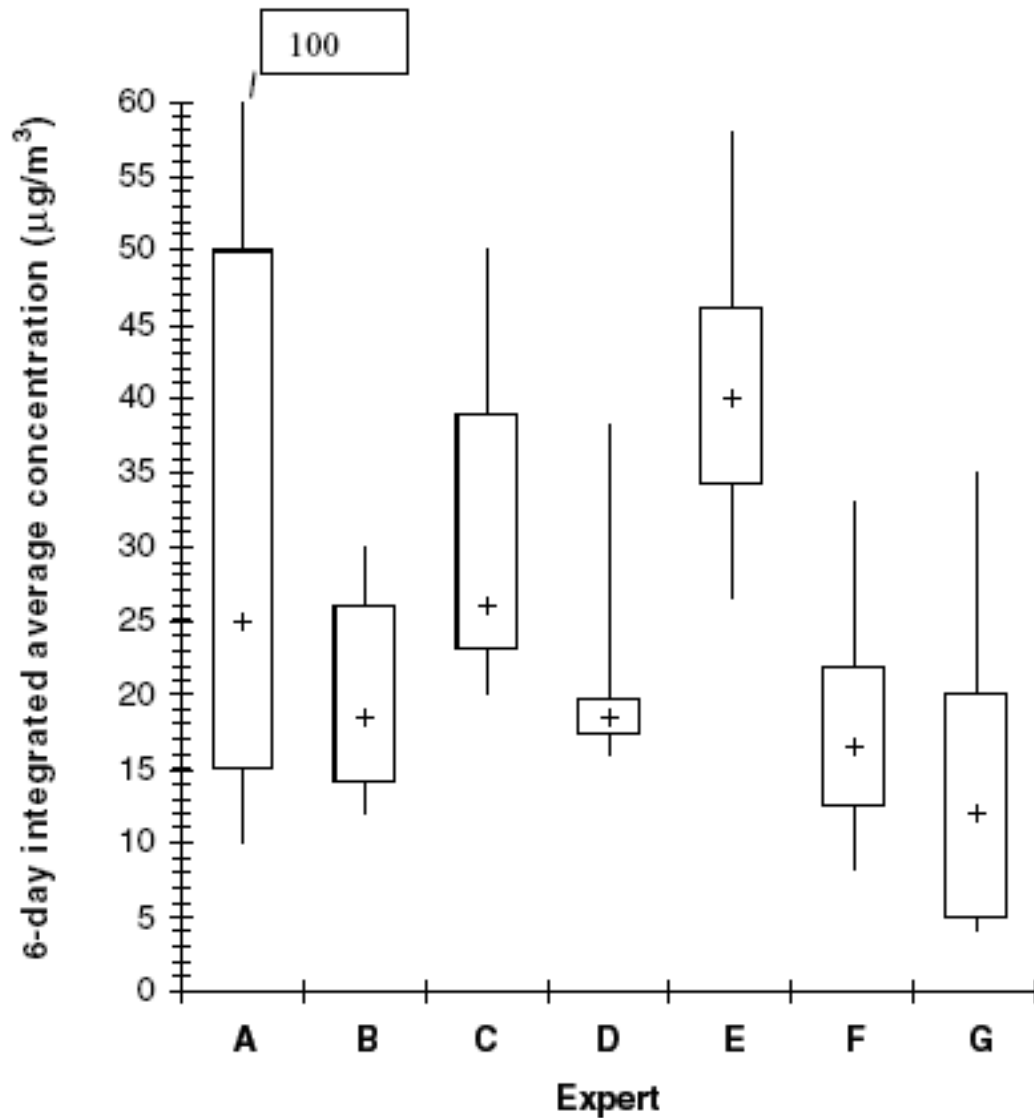
OEL = 50 ppm
(top and bottom 2 removed)

Prior Probability



Likelihood Distribution





True distribution of
90th percentile =
13.7 (10.2, 17.1)

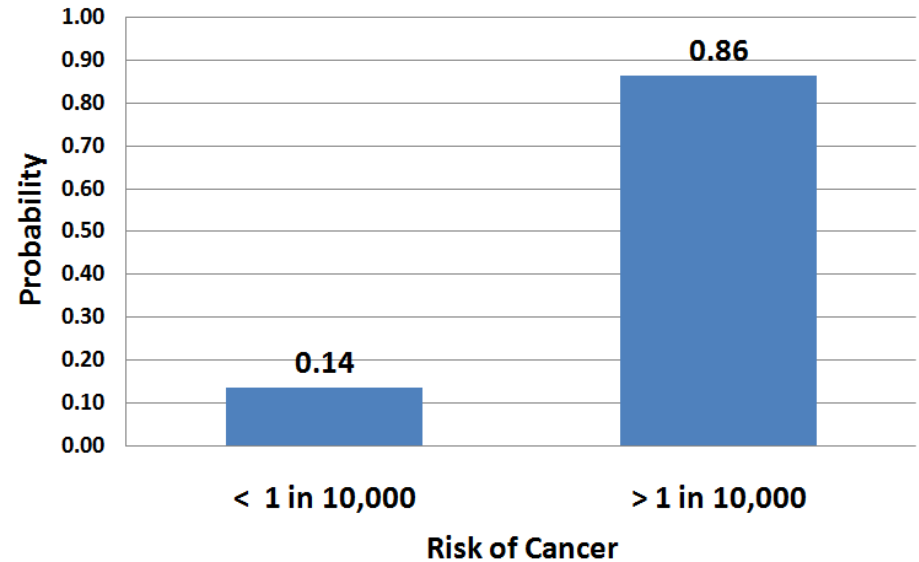
Source: Walker et al., J. of Exp. Analysis and Env. Epi., 11(4): 308-322. (2001)

Value used for risk of 1
in 10,000 = $13 \mu\text{g}/\text{m}^3$

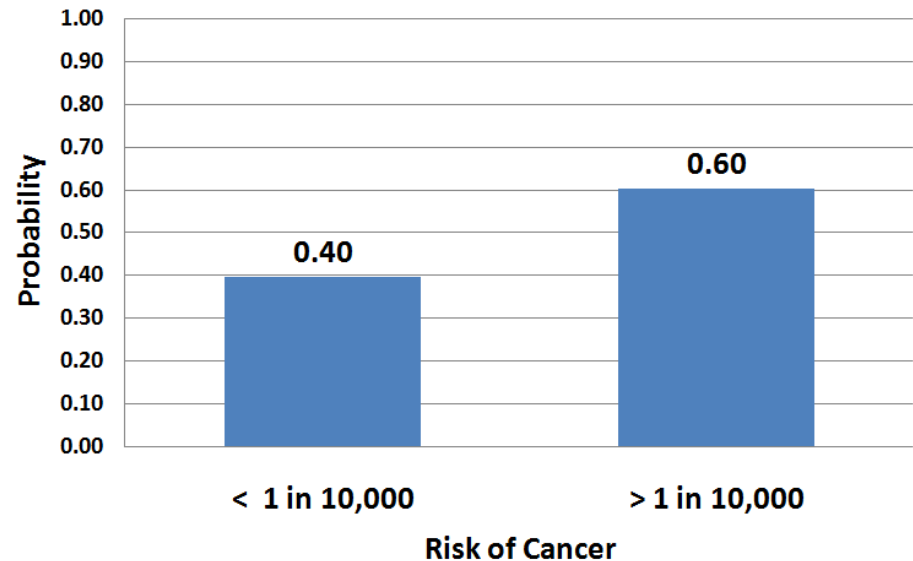
386 6-day personal
exposure measurements



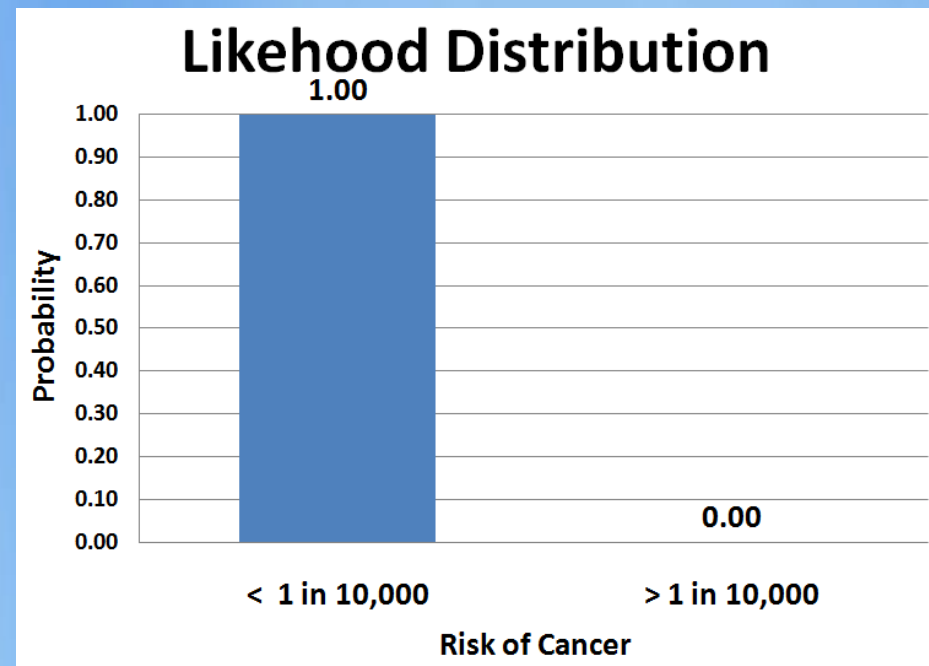
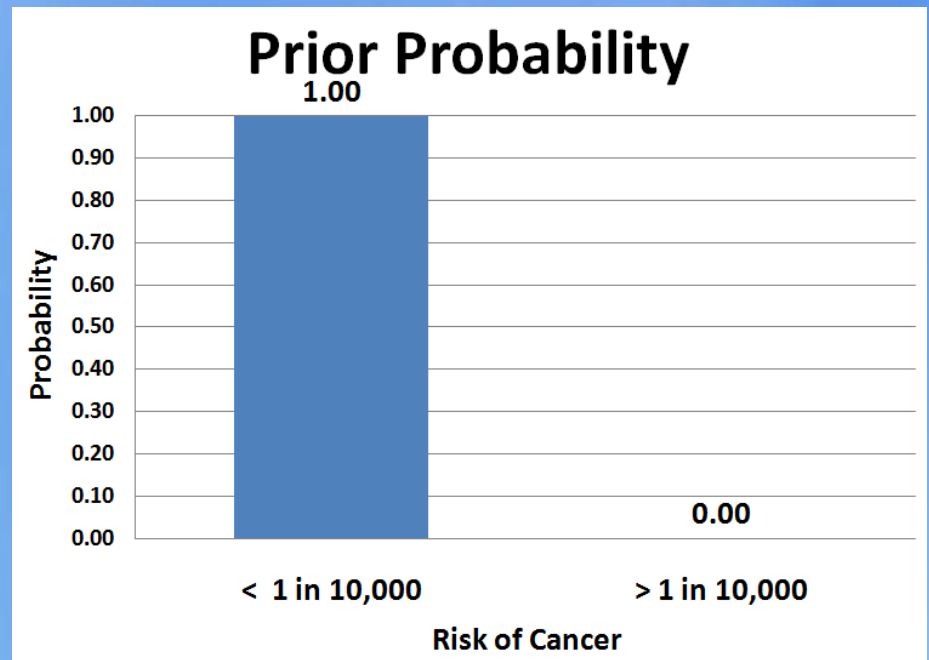
Prior Probability



Likelihood Distribution



Value used for risk of 1
in 10,000 = $45 \mu\text{g}/\text{m}^3$



Acceptance Criteria

If they can get you asking the wrong questions, they don't have to worry about the answers.

--Thomas Python

Acceptance Criteria

- What does an acceptable exposure distribution look like for a population?
... For an individual?
- What statistical measure and/or acceptance criteria should be used?

Common acceptance criteria in industrial hygiene

- Calculated $X_{0.95} < \text{OEL}$
- UCL of $X_{0.95} < \text{OEL}$
- UCL of $\bar{x} < \text{OEL}$
- Posterior Bayesian probability of exceeding $\text{OEL} < 5\%$
- One (or more) samples looked fine

Questions we're really trying to answer

- What is the likelihood of health effects given a particular exposure profile?
- What is the likelihood that an OSHA compliance officer will find an exposure that is in violation of the PEL?
- Overexposure = any TWA measurement exceeds the TWA TLV (allowing for a margin of measurement error)?

So which to use?

- Calculated $X_{0.95} < \text{OEL}$
- UCL of $X_{0.95} < \text{OEL}$
- UCL of $\bar{x} < \text{OEL}$
- Posterior Bayesian probability of exceeding $\text{OEL} < 5\%$
- One (or more) samples looked fine

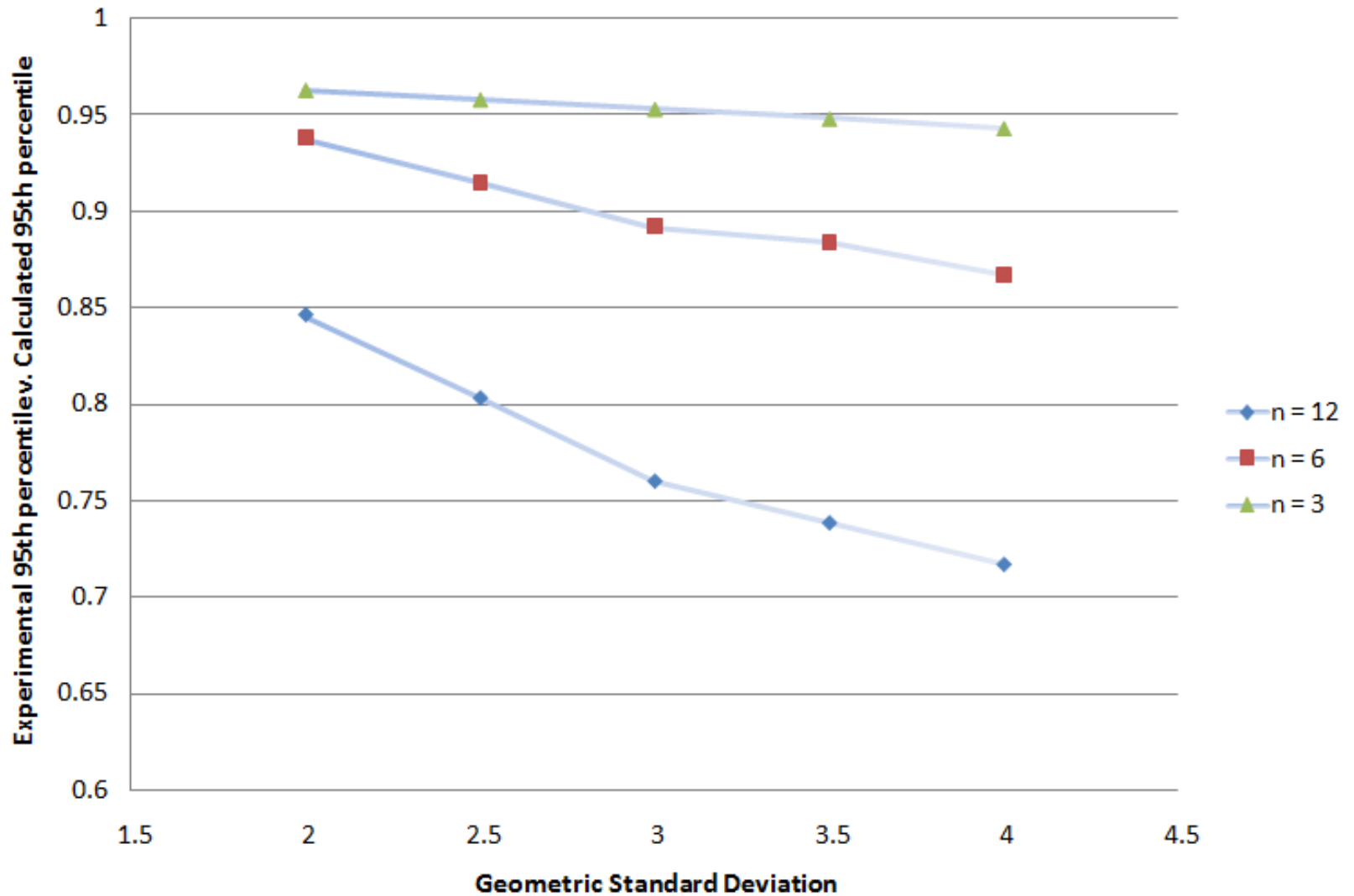
It depends . . .



Source: <http://www.vanbelle.org/presentations/narrative.pdf>

Calculated $X_{0.95} < OEL$

Effect of Sample Size and GSD on Calculated 95th percentile



Calculated $X_{0.95} < \text{OEL}$

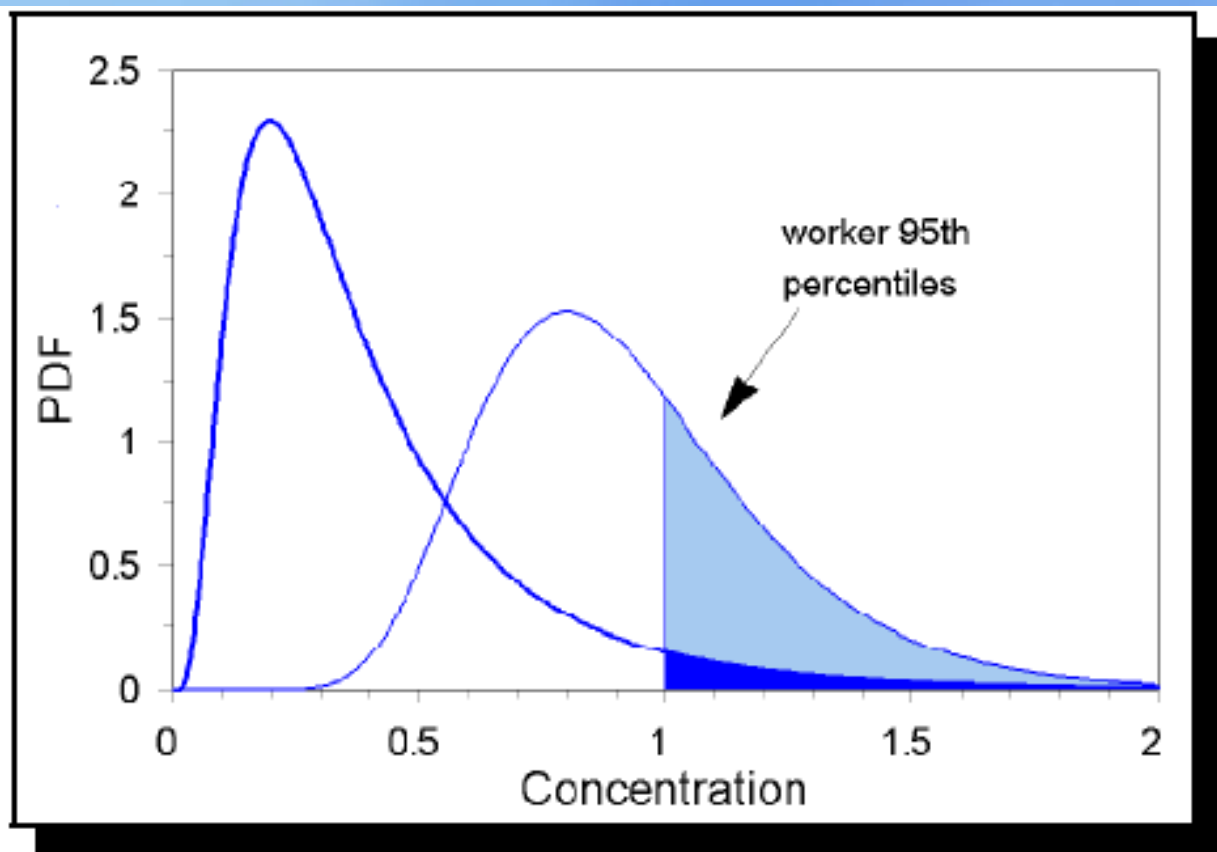


Figure 1: Distribution of worker exposures and distribution of worker “95th percentiles”. The geometric mean, geometric standard deviation, and heterogeneity coefficient for the group exposure profile are 0.3197, 2.0, and 0.2, respectively. Exactly 5% of the group exposure profile exceeds the TWA exposure limit of 1 ppm. In contrast, 35% of the workers have individual 95th percentile exposures that exceed the limit.

Recommendations to account for inter-worker variability

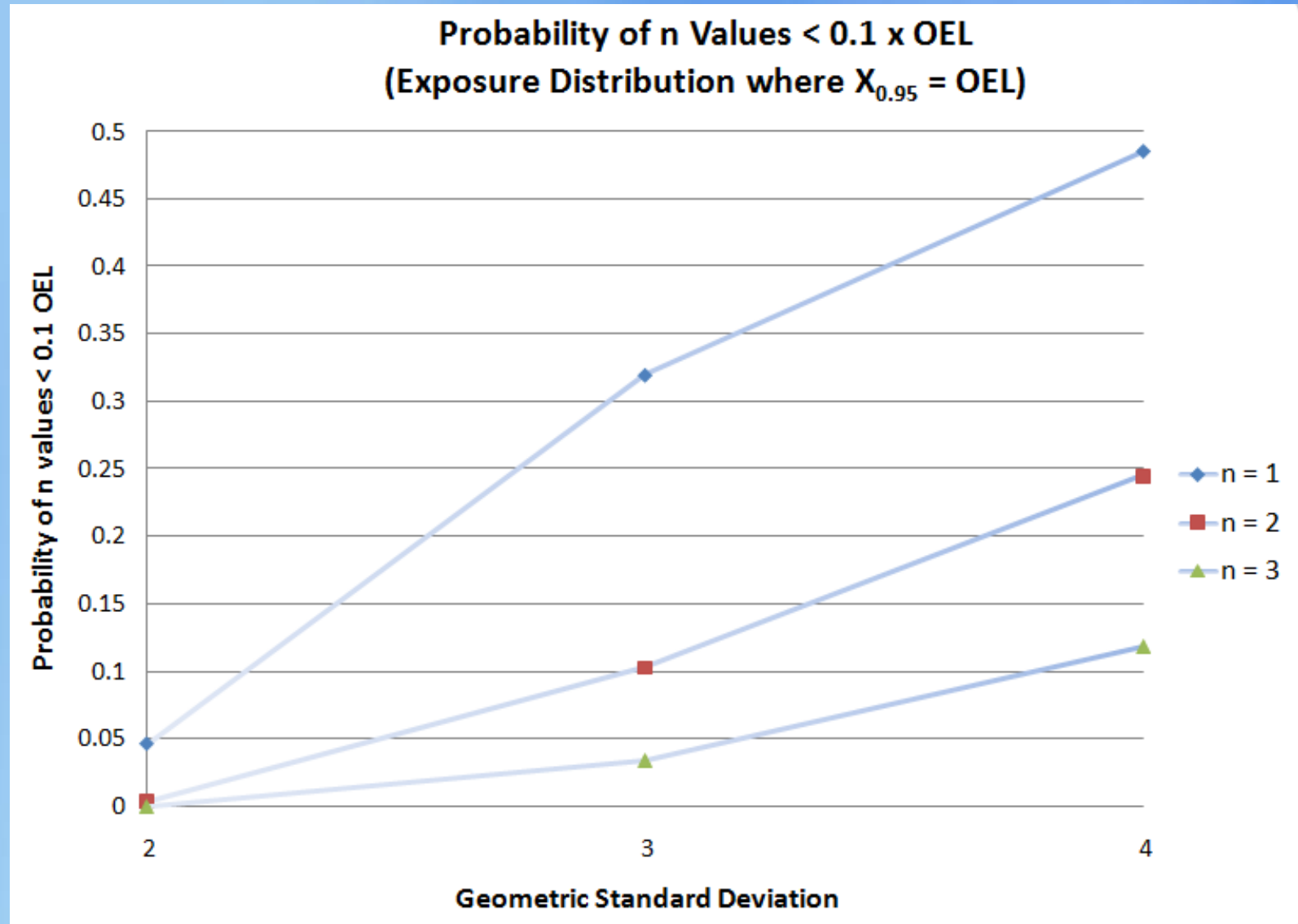
- Group exceedance fraction < 0.01
- $X_{0.95} < 0.5 \times \text{OEL}$
- $\text{GM} < 0.1 \times \text{OEL}$

Source: Hewett, P. Technical Report No. 05-02. January 2005.

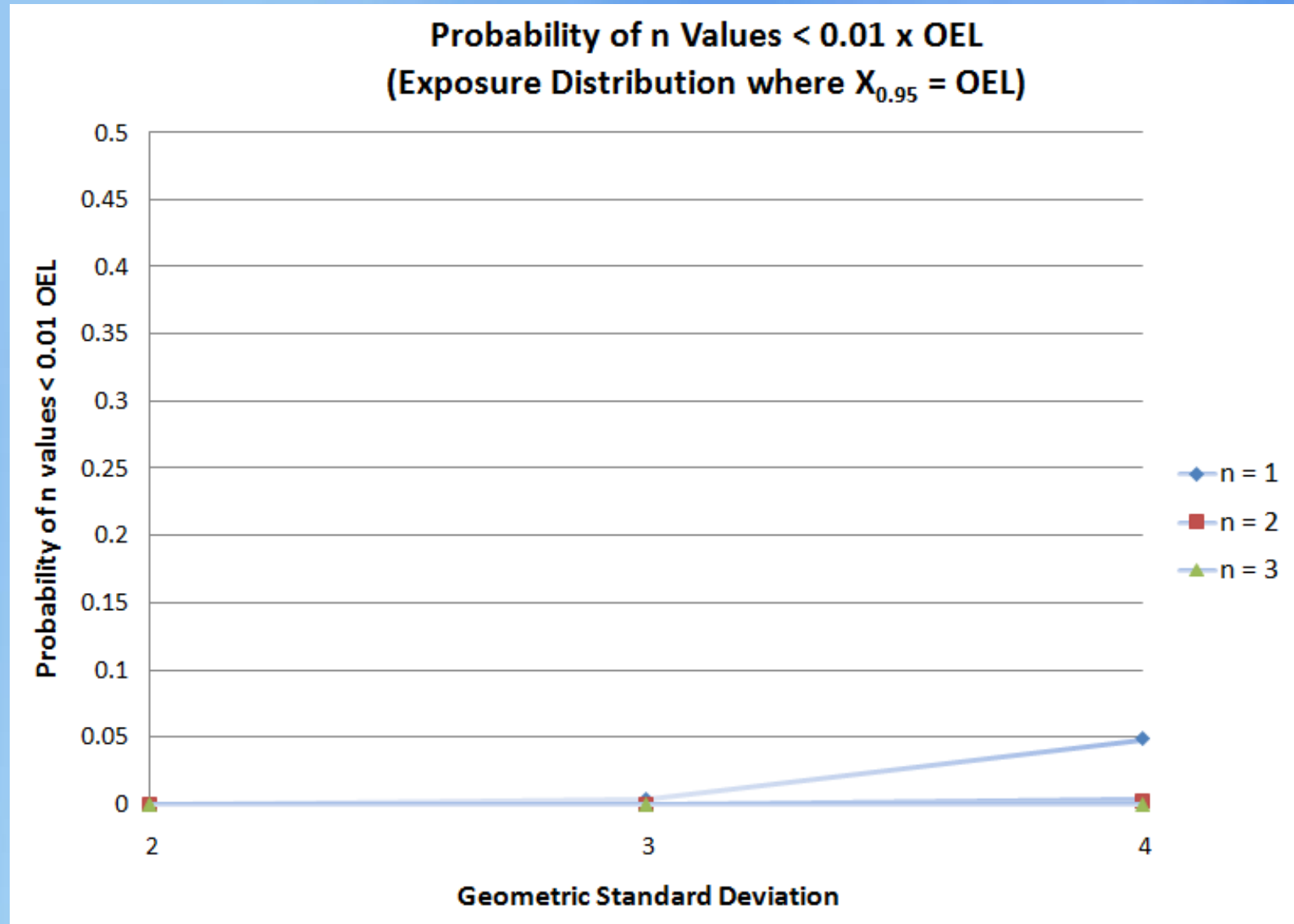
- Another rule of thumb: “The width of the confidence interval decreases rapidly until 12 observations are reached and then decreases less rapidly”.

Source: <http://www.vanbelle.org> Rule 1.10 (August 2003)

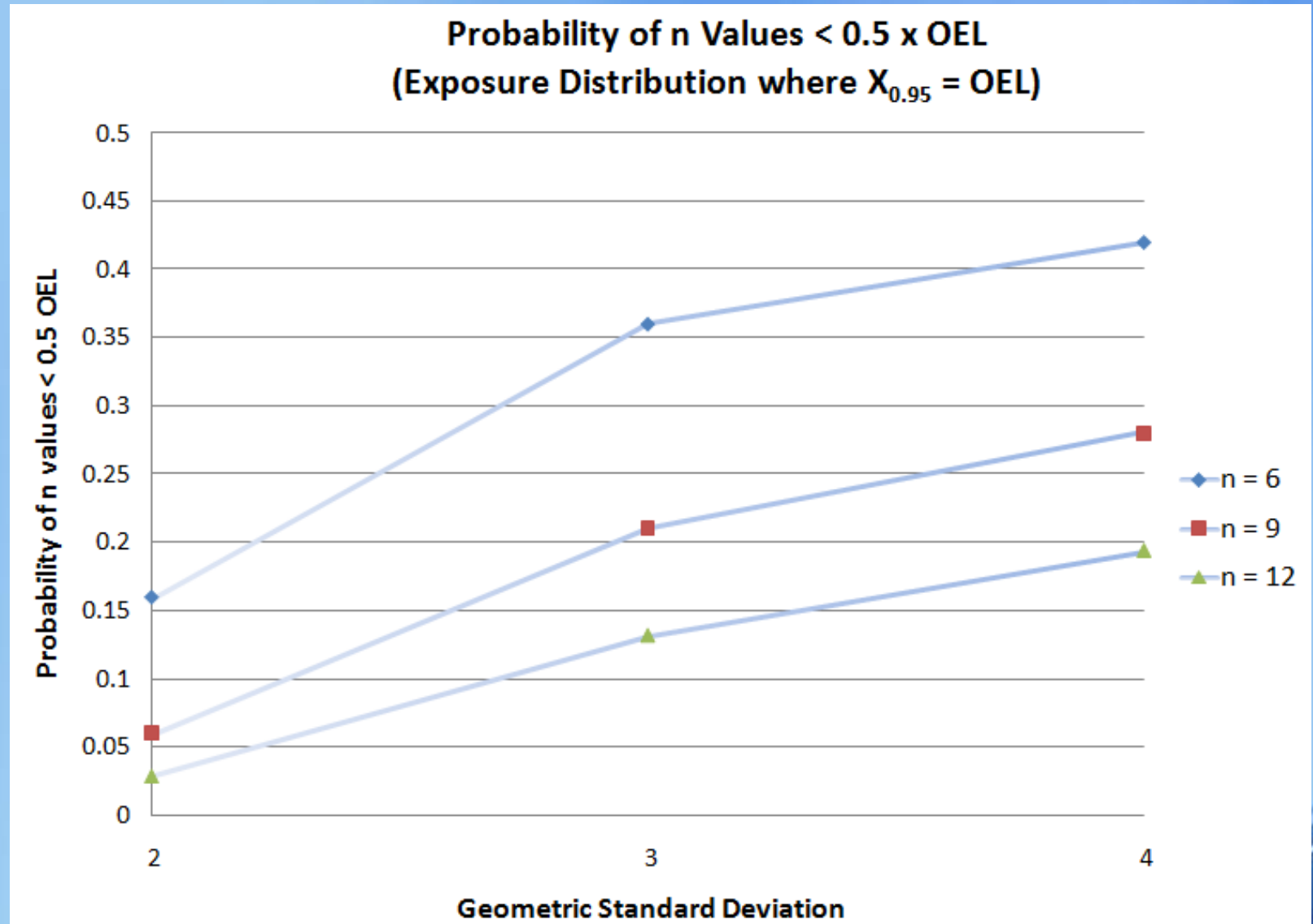
One (or more) samples looked fine



One (or more) samples looked fine



One (or more) samples looked fine



Low Exposure Values

- 3 consecutive random samples $< 0.1 \times$ OEL (and none over $0.1 \times$ OEL!) are a good indicator that $X_{0.95} < \text{OEL}$
- Even 1 random sample, but preferably 2 random samples $< 0.01 \times$ OEL are a good indicator that $X_{0.95} < \text{OEL}$
- For larger, uncensored data sets and for exposures closer to the OEL, use statistical tools

Bayesian Statistics: Importance of accurate priors

- Bayesian statistics may be very useful in assessing control banding systems – but realistic estimates on which to base prior probabilities are critical

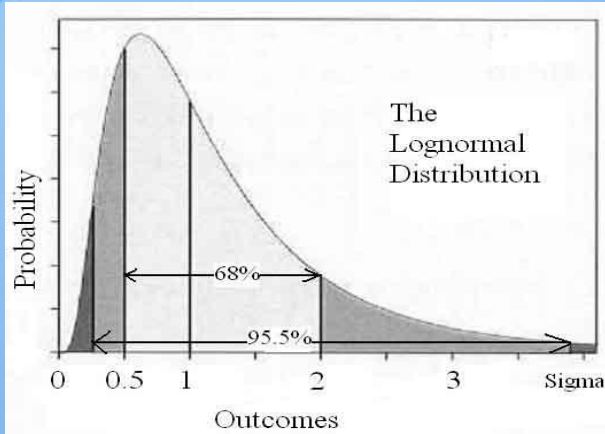
Bayesian Statistics

$$P(A|B) = \frac{P(B|A)P(A)}{P(B|A)P(A) + P(B|A^c)P(A^c)}$$

$$f_X(x|Y=y) = \frac{f_{X,Y}(x,y)}{f_Y(y)} = \frac{f_Y(y|X=x) f_X(x)}{f_Y(y)} = \frac{f_Y(y|X=x) f_X(x)}{\int_{-\infty}^{\infty} f_Y(y|X=\xi) f_X(\xi) d\xi}$$

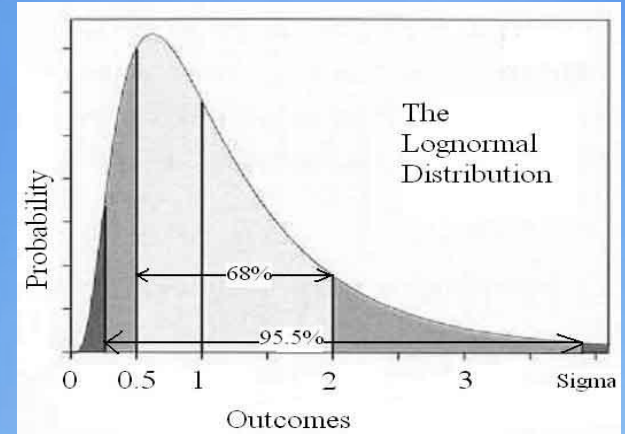


Prior Probability

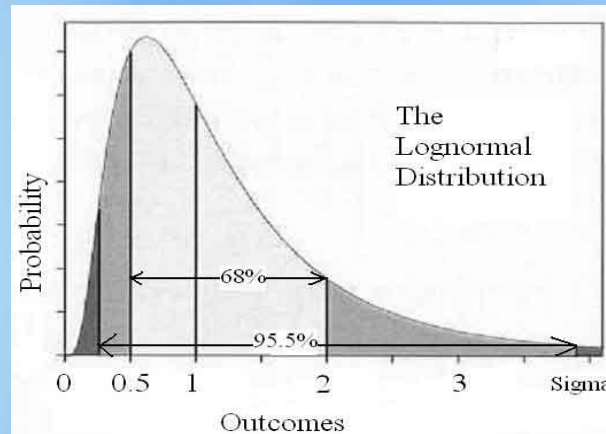


Extract sample
or subject

Likelihood Distribution



Posterior Probability



2009 Super Bowl Odds

Posted on Tuesday, February 05, 2008

“Prior” Probabilities

- Are we good at predicting probabilities?

- New England Patriots: 3:1
- San Diego Chargers: 11:2
- Indianapolis Colts: 12:1
- Dallas Cowboys: 14:1
- Pittsburgh Steelers: 20:1
- New York Giants: 25:1
- Green Bay Packers: 25:1
- Jacksonville Jaguars: 25:1
- New Orleans Saints: 25:1
- Cincinnati Bengals: 28:1
- Philadelphia Eagles: 35:1
- Denver Broncos: 40:1
- Cleveland Browns: 50:1
- Washington Redskins: 50:1
- Chicago Bears: 50:1
- Minnesota Vikings: 50:1
- Detroit Lions: 50:1
- Carolina Panthers: 50:1
- Tampa Bay Buccaneers: 50:1
- Seattle Seahawks: 50:1
- San Francisco 49ers: 50:1
- Arizona Cardinals: 50:1

Bayesian Decision Chart

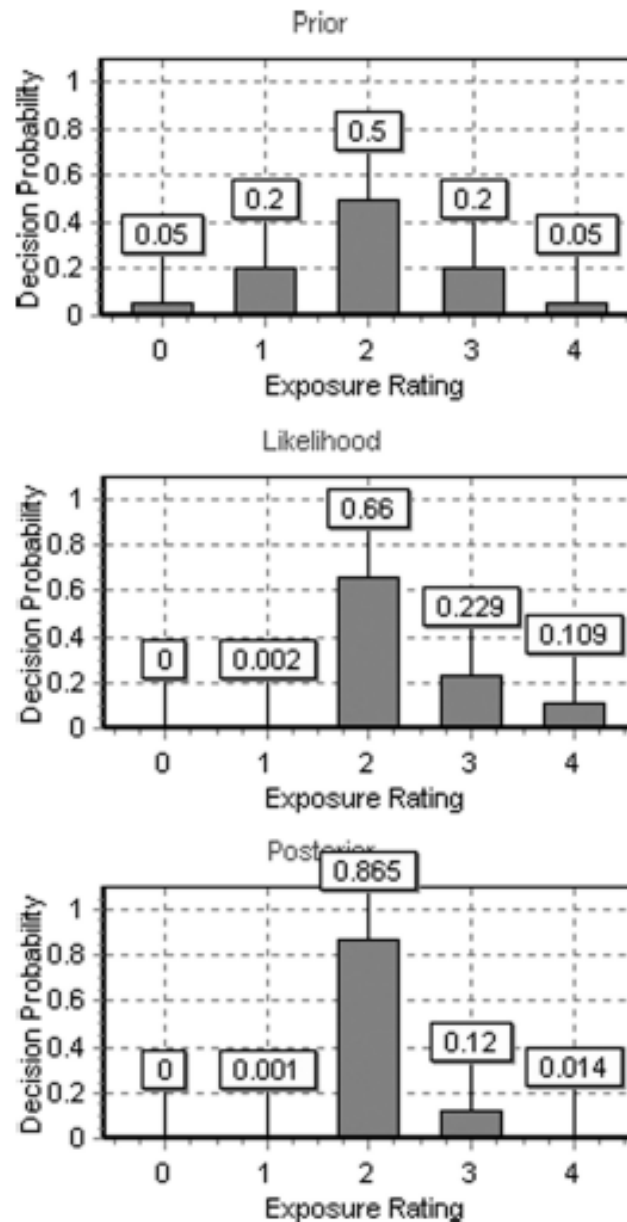


FIGURE 6. Decision charts for the informative prior scenario: $x = \{0.20, 0.05, 0.05\}$ and Limit = 1 ppm

Control Banding Approach to Managing Risk

Hazard
Identification

Qualitative/Semi-
Quantitative Health
Assessment

How accurate is our
assessment of the health risk?

How accurate is the
exposure prediction?

Exposure
Prediction

Risk
Characterization

How well are
exposures controlled?

Risk
Management

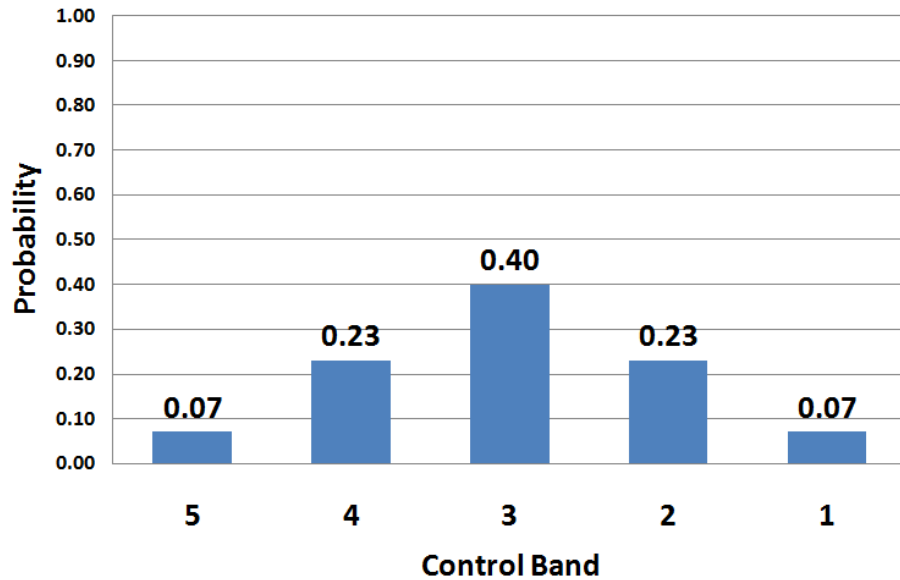
Hypothetical Pharmaceutical Control Banding Scheme

Control Band	Exposure band ($\mu\text{g}/\text{m}^3$)
1	> 100
2	20 - 100
3	2 - 20
4	0.2 - 2
5	< 0.2

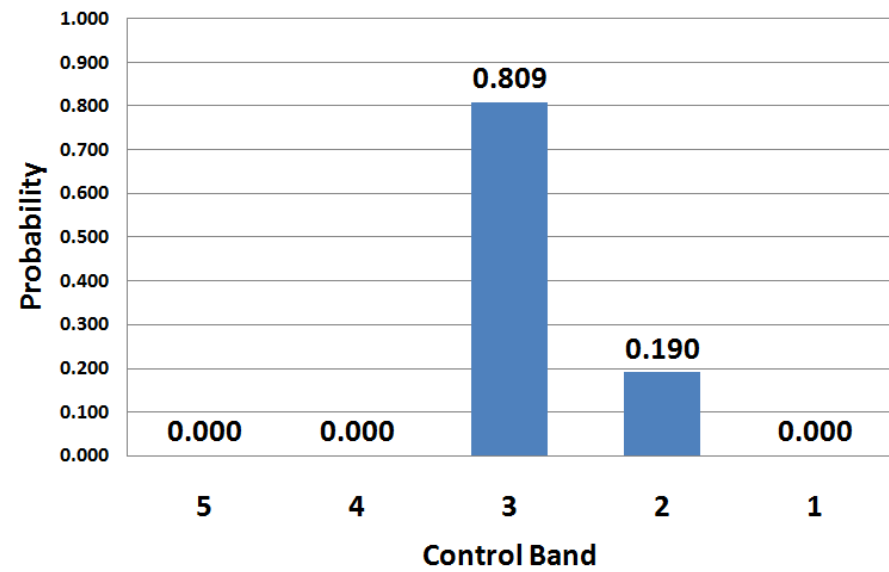
Model Data

- Control Band 3 Substance (2-20 $\mu\text{g}/\text{m}^3$)
- GM = 5.0 $\mu\text{g}/\text{m}^3$
- GSD = 2.5
- 95th percentile = 22.5 $\mu\text{g}/\text{m}^3$

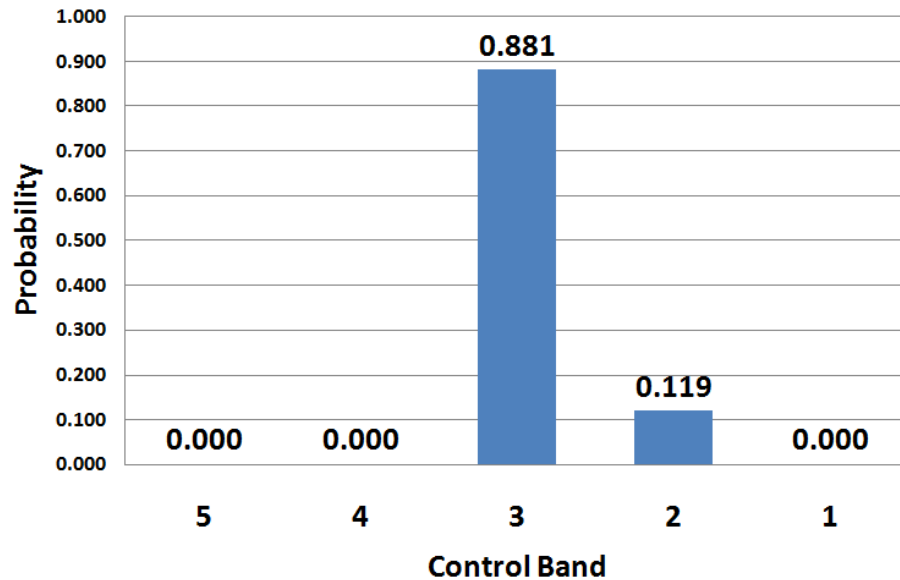
Prior Probability



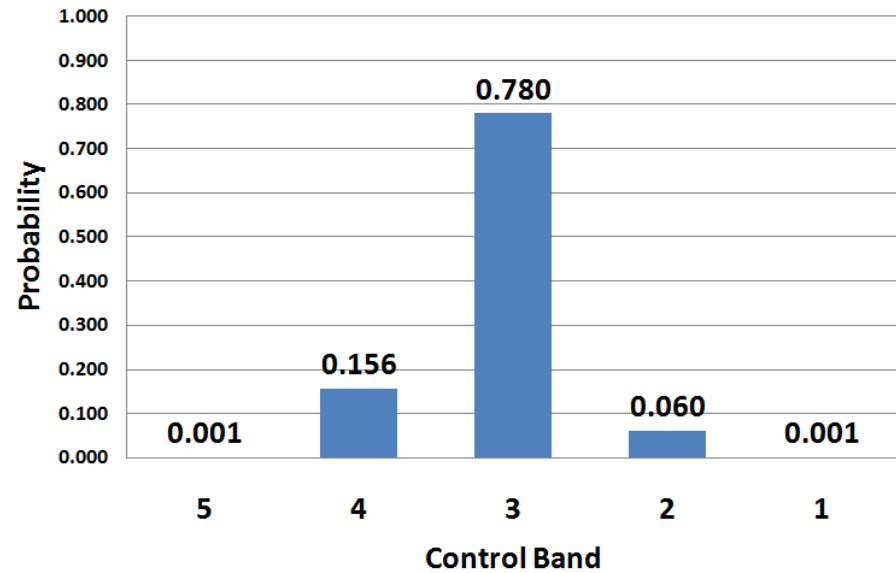
Likelihood Distribution



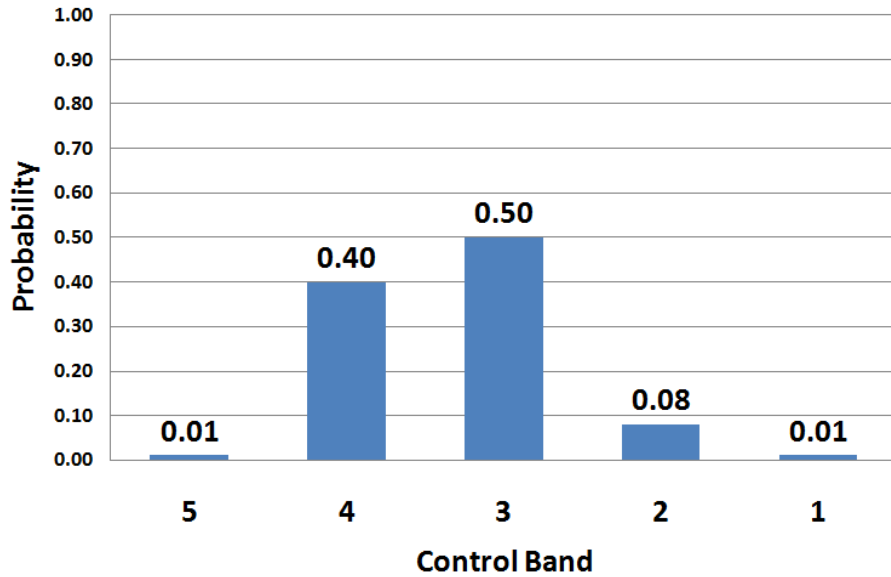
Posterior Probability



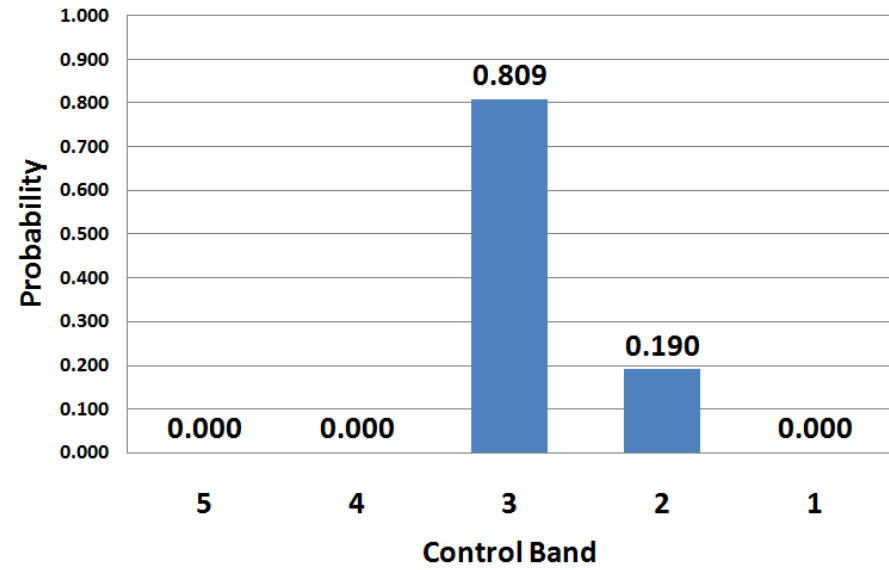
True Probability



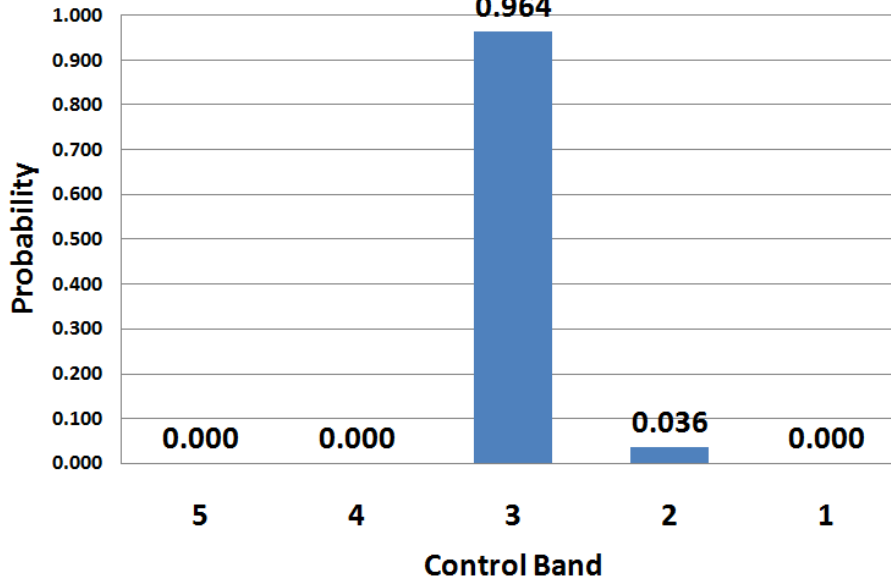
Prior Probability



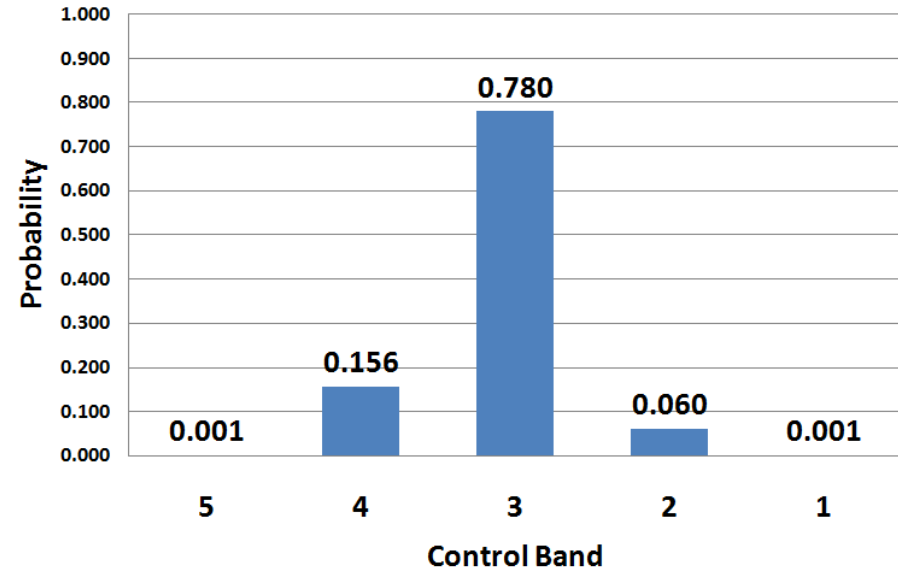
Likelihood Distribution



Posterior Probability



True Probability



Control Banding Assessment

- Data from similar processes with similar chemicals can be used to generate a realistic informative prior
- Verification data should show that acceptance criteria are met ...
- But acceptance criteria depend on context – criticality, personal preference, feasibility, size of the data set

Control Banding Implications

- Bands should be at least one order of magnitude wide
- Exposure should be “acceptable” at the top end of the band
- Controls should be designed to achieve the bottom end of the band