Peeling the Onion of Pathogen Standards for Foodborne Pathogens

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Perspective

- Brief Review of Standard Scheme
- Onion Layers
- Redefining Performance
- Tools to Rebuild the Onion

Food Safety Objectives

- The primary goal of an FSO is to translate a risk level to a measure that can be applied by food processors.

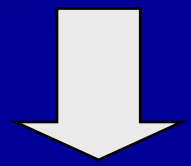
ICMSF:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

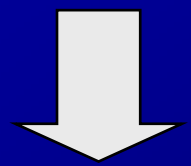
- R = reductions, I= Increases

Overall Process

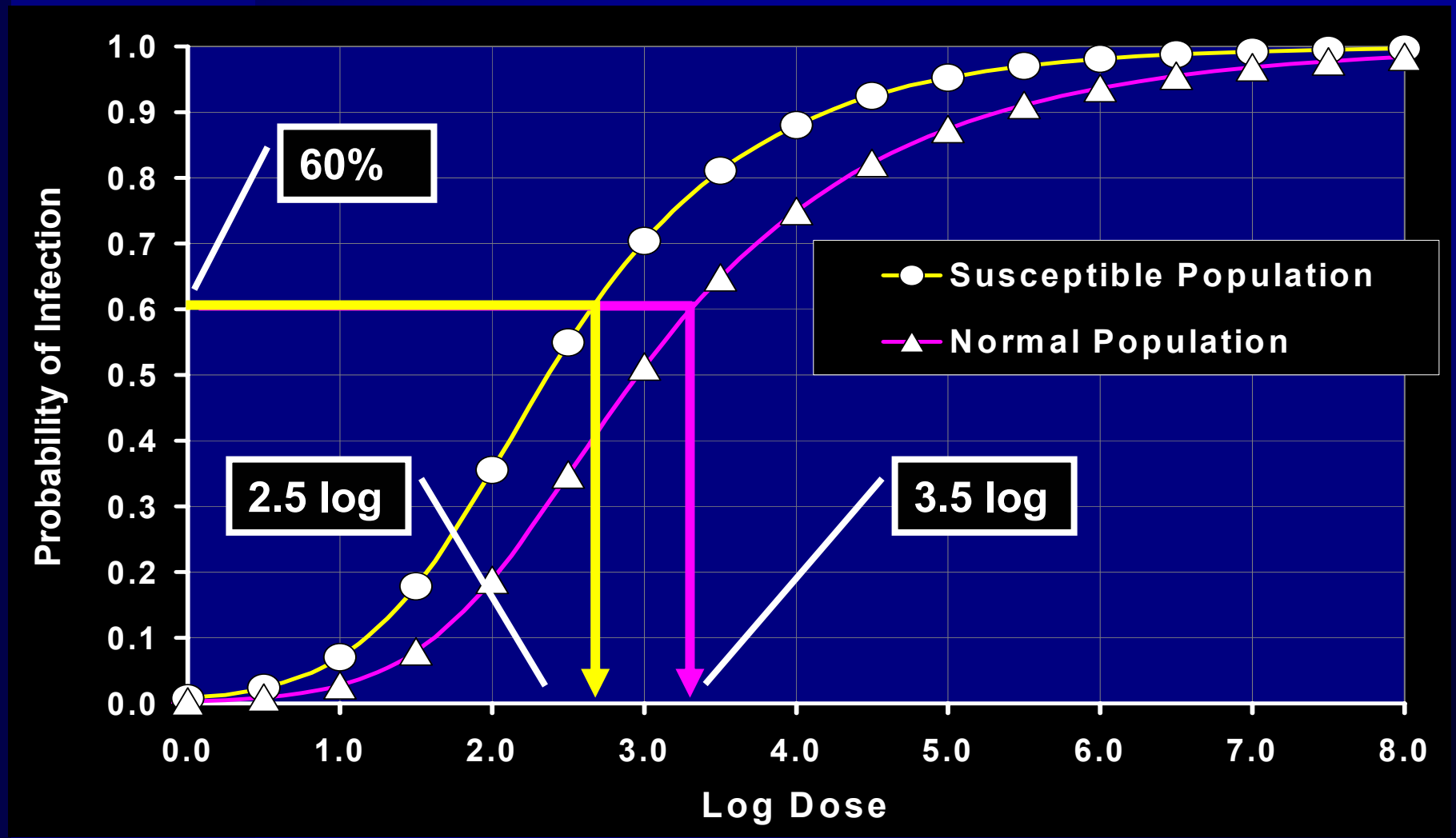
Acceptable Level of Protection



Food Safety Objective



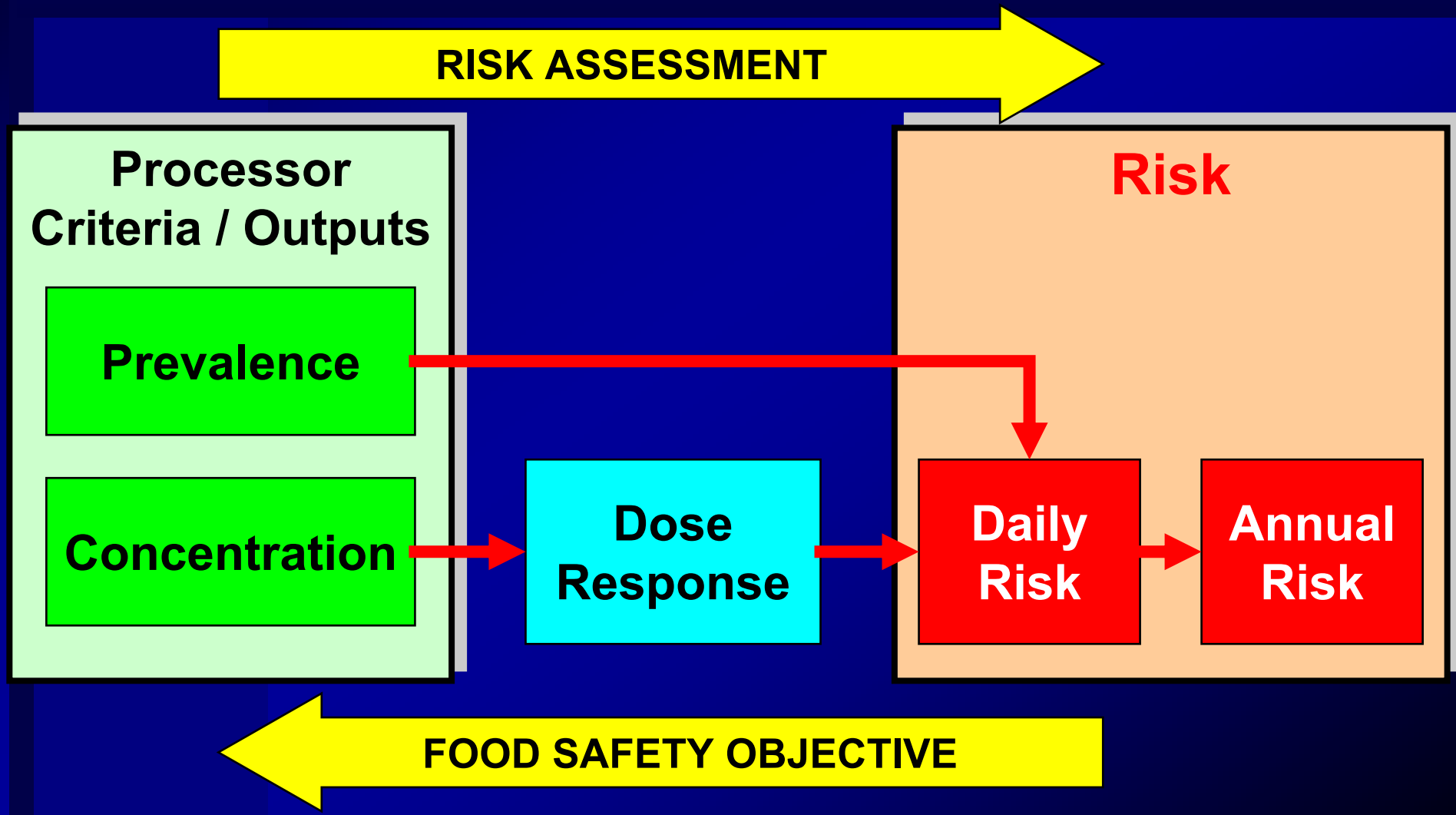
Performance Standard


Probability of Infection
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0.0
1.0
2.0
3.0
4.0
5.0
6.0
7.0
8.0
Log Dose
60%
2.5 log
3.5 log
Susceptible Population
Normal Population

Food Safety Objective

- Attempt to define a tolerable and achievable risk level upon which processing criteria can be set.
- Risk level needs to be translated to conditions that are measurable conditions in processing plants.

Food Safety Objective



Food Safety Objective

- Goal: to back-calculate tolerable and achievable risk levels to processor outputs

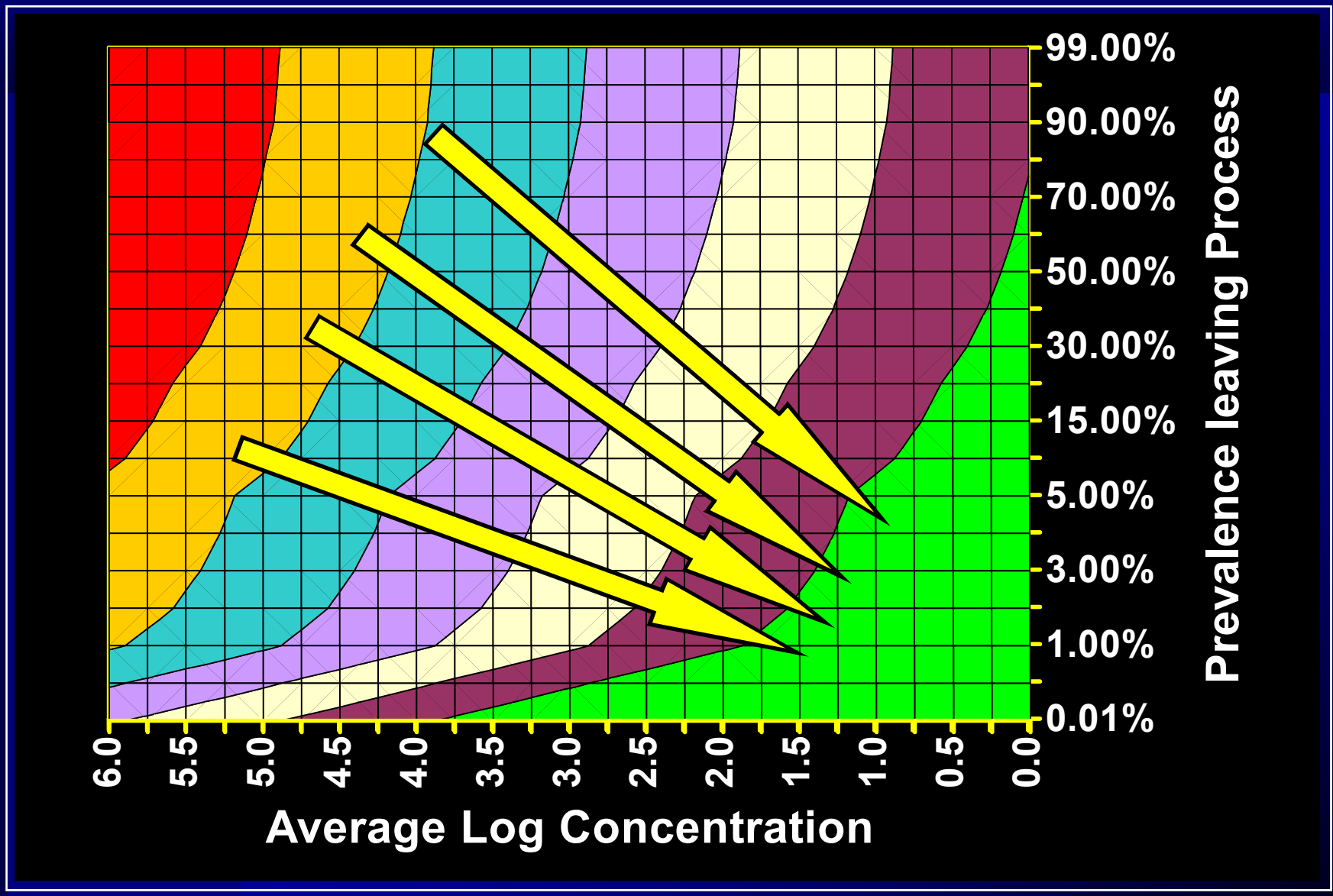
Selected Onion Layers

- Critiques of FSO Scheme
- Explicit Valuation of Outcomes
  - Population vs. Individual
- Accounting for Downstream Handling
- Indirect Risk Mitigation
  - Compliance
  - Inspection
  - Verification Sampling
  - Consumer Education and Labelling
- Defining Total Performance
  - Public Health
  - Food Companies

Critiques of FSO Schemes

- Simplicity is not always helpful
  - Are we reversing progress?
- Both prevalence and concentration matter
- Where do variability and uncertainty fit in?
  - Mean on the Log Scale
  - Back-calculation is very challenging
  - ICMSF eq. is not compatible with QMRA
- Re-contamination is not a log-additive phenomenon

The Goal in 2-Dimensions

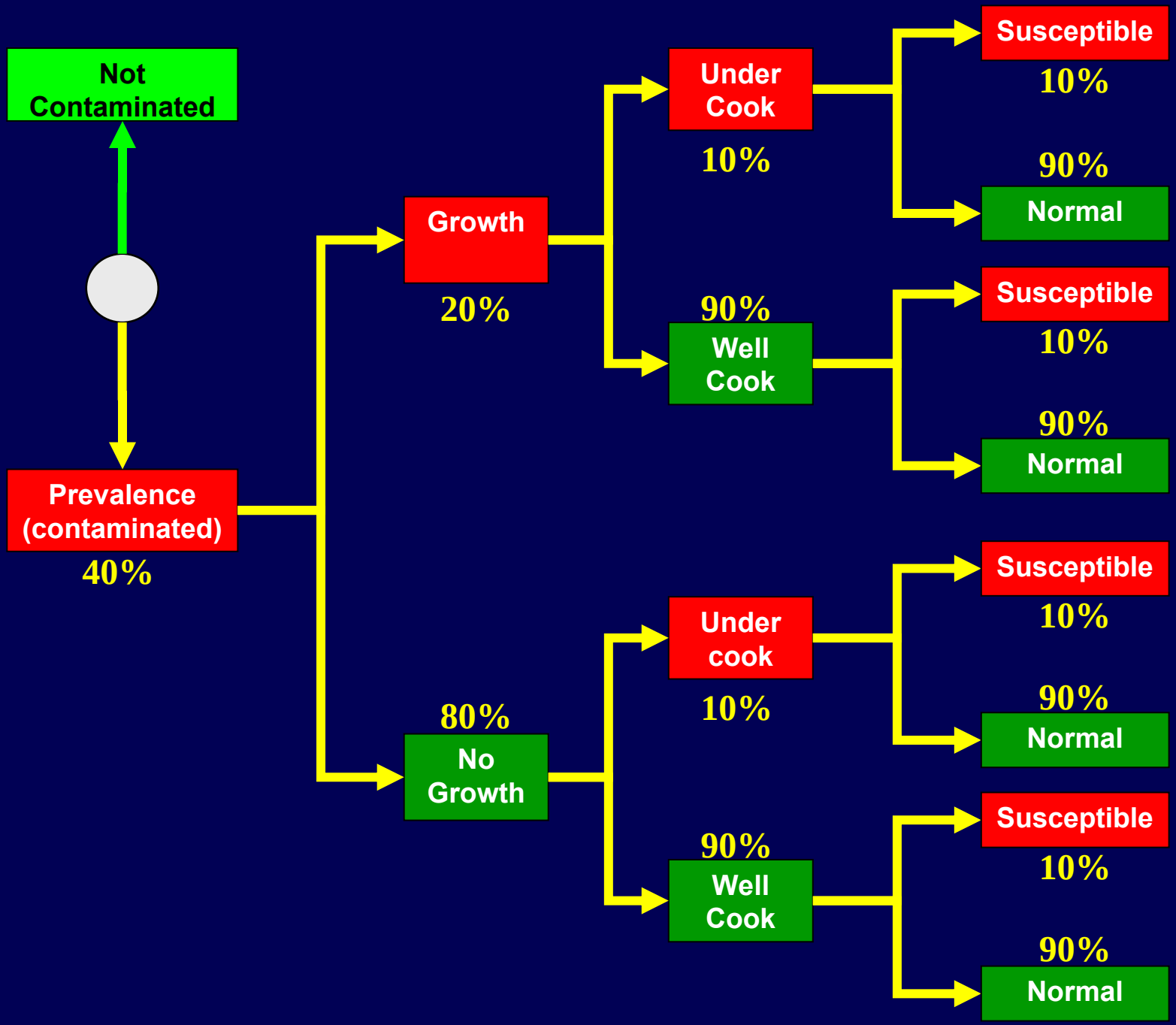


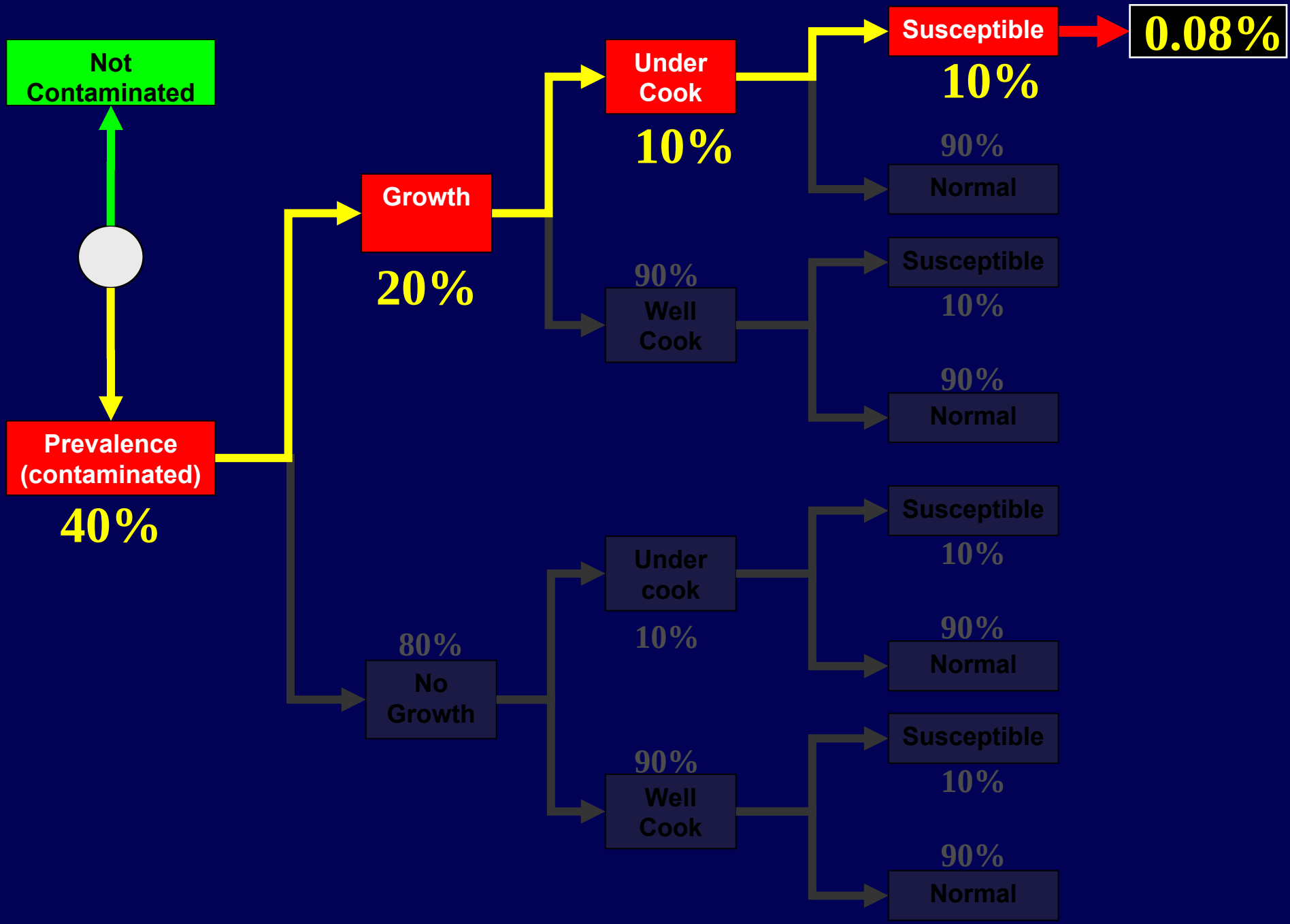
Explicit Valuation of Outcomes

- Variable Burden of Disease across Hazards
- Net Risk from a Class of Hazards
- Suite of Measures:
  - Per Serving
  - Per Kg
  - Per Million Persons
  - Hybrid Measures

Downstream Handling

- There are a sequence of events between process and risk
- These events need to be considered
- Can be accounted for as realistically as possible or conservatively.
- The following is a crude simplification


Not Contaminated
Prevalence (contaminated)
40%
Growth
20%
No Growth
80%
Under Cook
10%
Well Cook
90%
Under cook
10%
Well Cook
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal


Not Contaminated
Prevalence (contaminated)
40%
Growth
20%
Under Cook
10%
Susceptible
10%
0.08%
90%
Normal
90%
Well Cook
Susceptible
10%
90%
Normal
80%
No Growth
Under cook
10%
Susceptible
10%
90%
Normal
90%
Well Cook
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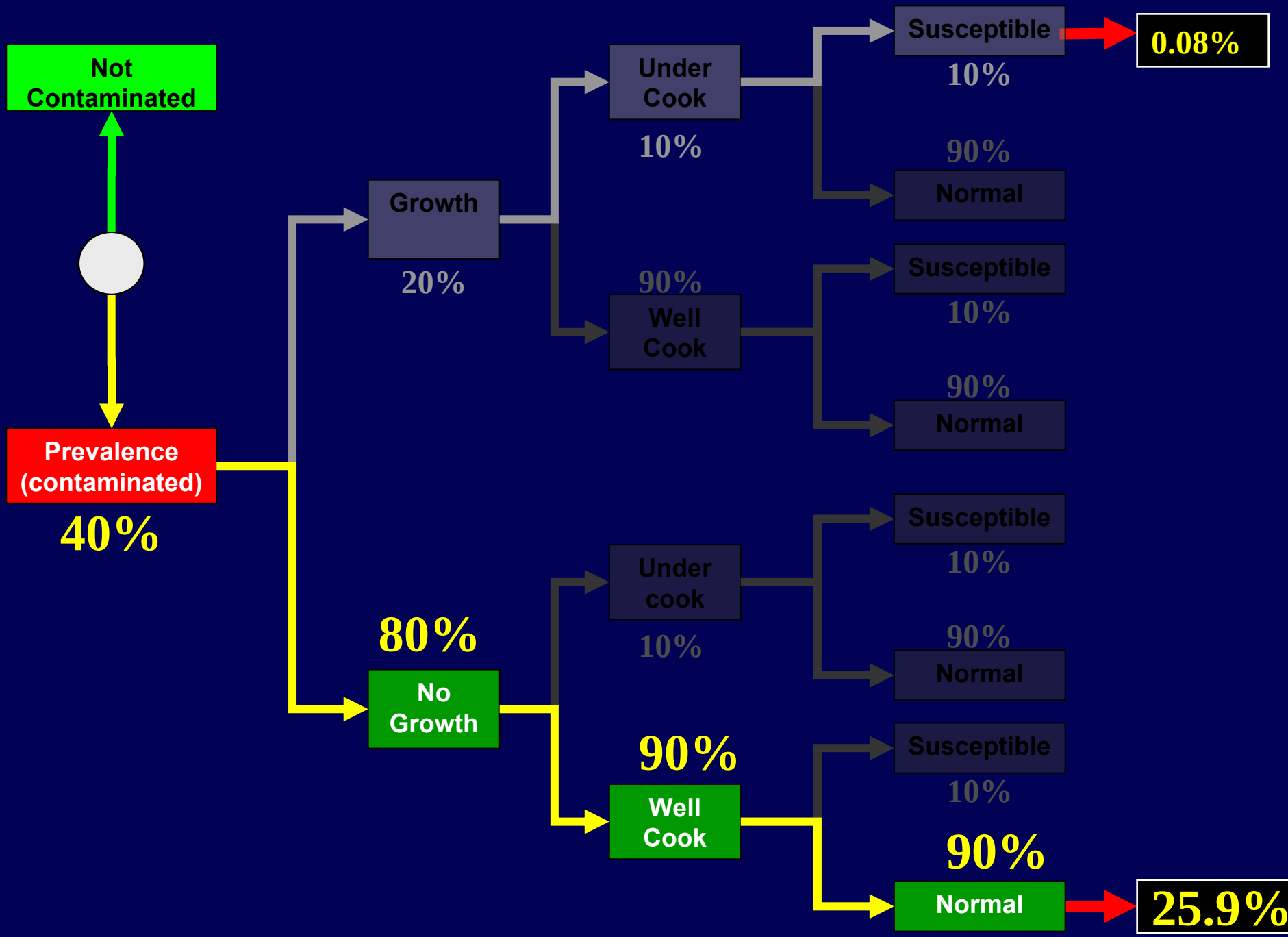
Normal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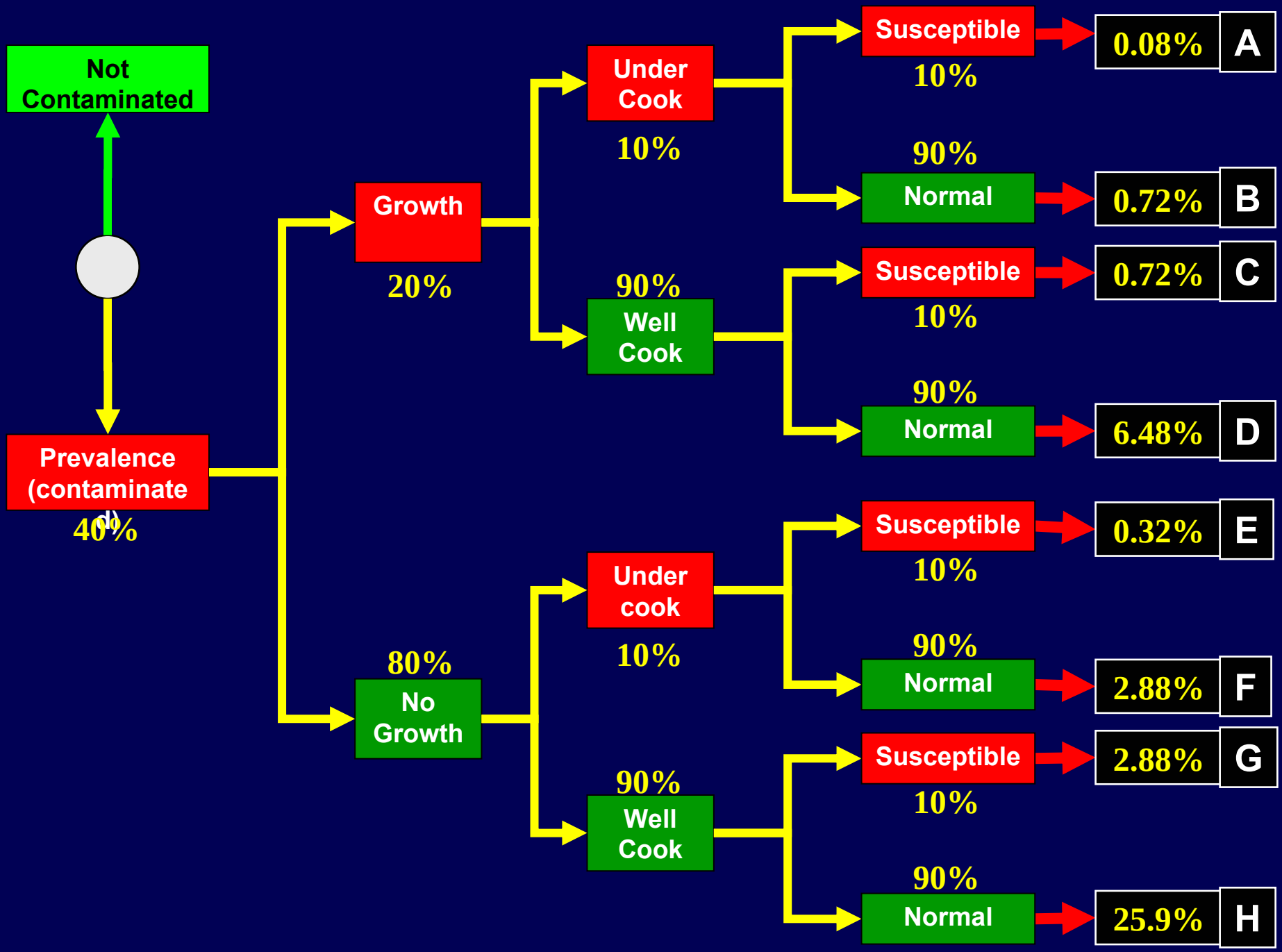
Normal
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal
90%
0.08%
25.9%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10%
Normal
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal
90%
Susceptible
10%
Normal
90%
0.08%
A
0.72%
B
0.72%
C
6.48%
D
0.32%
E
2.88%
F
2.88%
G
25.9%
H

- **Pathway A**
  - Greatest risk when it occurs
  - Lowest likelihood of occurrence
- **Pathway H**
  - Lowest risk when it occurs
  - Greatest likelihood of occurence
- **Pathway F**
  - Intermediate rank in both categories

	A	F	H
Annual Odds (1 in)	1000	1000	1000
Avg. Conc. (Log CFU/g)	-3.02	-1.59	1.41
1 cell in: (grams)	1040	39.00	1.00
Cells in: (5000 grams)	4	128	129,000

Defining Reasonable Downstream Scenarios

- Is it possible to define ‘reasonable’ limits on downstream handling
- Extreme Temperature Abuse
- Children Consuming Raw Beef

Hands-off Risk Mitigation

- Compliance and Enforcement
- Inspection
- Verification Sampling
- Recall
- Consumer Education
- Facilitation

- Performance Standards for the Regulator?

Redefining Performance

- Ethical Dimensions
  - Individual and Population
  - Shared Burden
- Management Impact
  - Innovation-Friendly
- Burden of Uncertainty
  - Assured versus Designed Safety
  - Resources to Promote Assurance
- Inspection, Verification, Auditing and Sampling
- Multiple Pathogen, Cross-Hazard?

Process Variables

- Prevalence and Concentration
- Lot Size and Pooling
- Pre- and Post-Sampling
  - Indicators
- Formulation
- Package Instructions

- No real need to exclude any viable risk mitigation

Analytica - [Result - Mean Burden of Disease per 1M Servings]

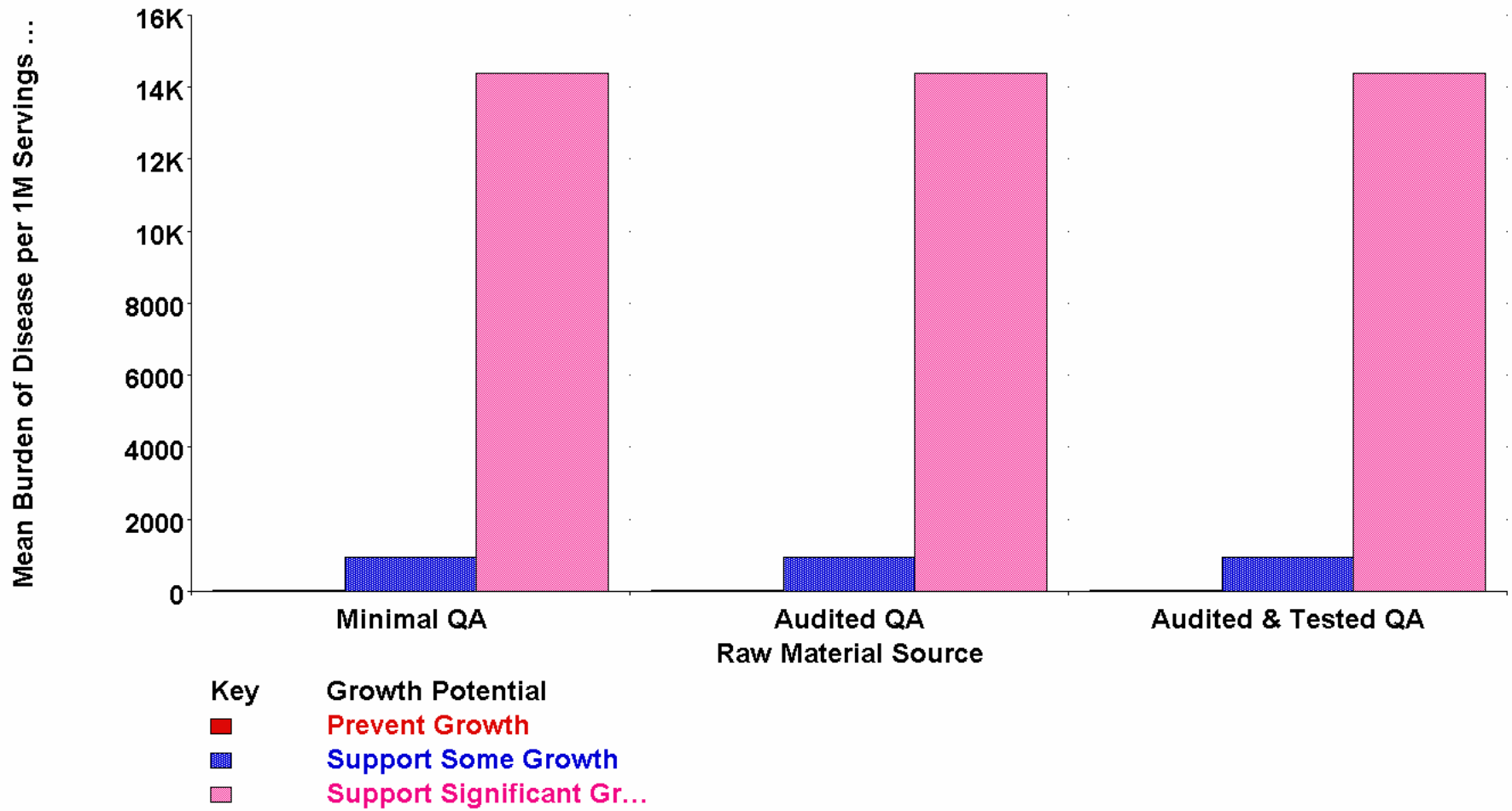
File Edit Object Definition Result Diagram Window Help

Mid Value of Mean Burden of Disease per 1M Servings (DALYs/Million Servings)

Lethality Target	5
Post-Lethality Process Inspection	Infrequent Inspection
Raw Material Prevalence	1%
Pre-Lethality Process Inspection	Frequent Inspection
Pathogenicity	Mild
Consumer Education	Poor
Consumption Pattern	Normal

Key: Growth Potential

X Axis: Raw Material Source



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Tools to Rebuild the Onion

- Don’t hide the complexity
  - Technically feasible
  - Communication is the only barrier
  - Exploit and facilitate flexibility
- If it sounds too simple …

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