The Journey to Fully Risk-Based Decision-Making in Food Regulatory Organizations

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Understanding, Managing and Communicating Risk ™

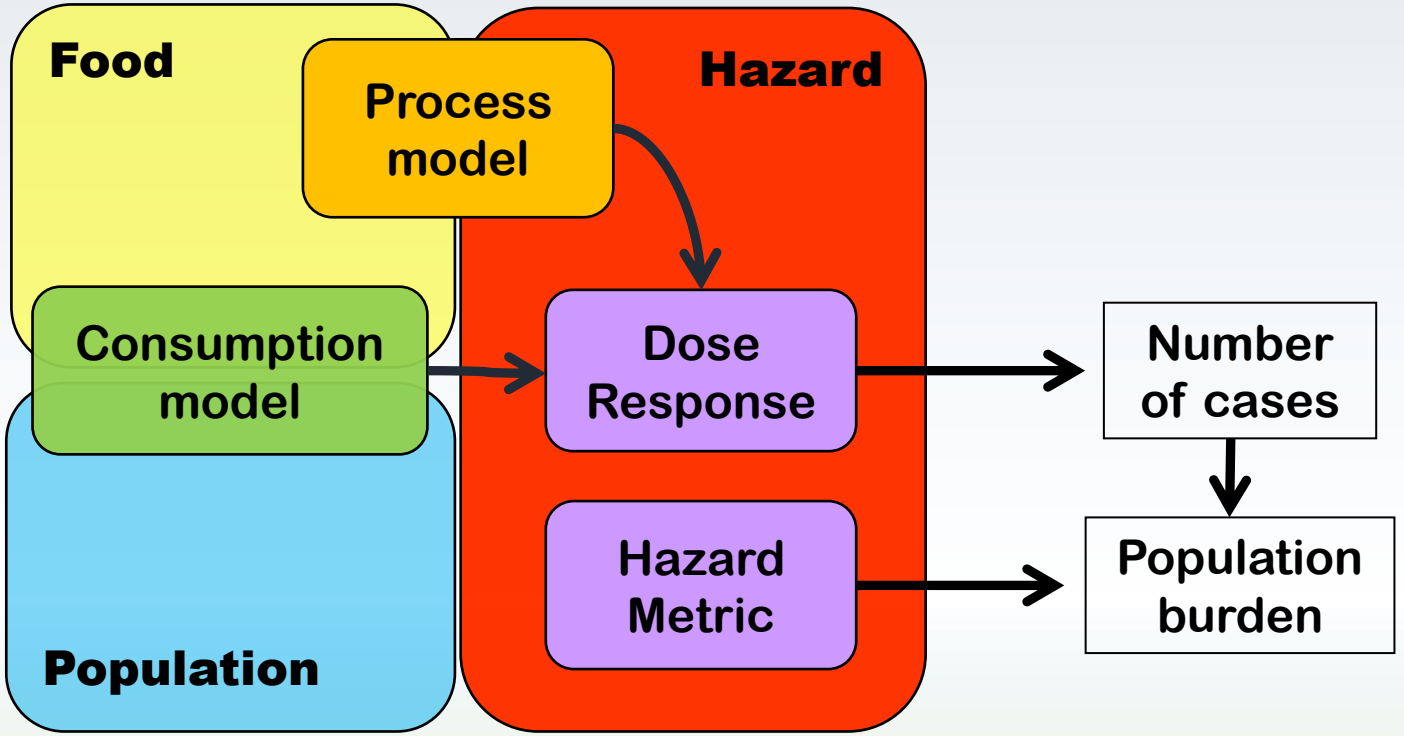
Risk-based

refers to activities or decisions where an estimate of the level of **risk**, the level of risk reduction, or the cost-effectiveness of risk reduction is explicitly considered in conducting the activity or in making decisions

Risk-Informed

similar to ***risk-based***, but often used to explicitly acknowledge that other factors, other than measures of risk are incorporated into the decision-making process.

The 7 Elements of a Risk Scenario



Is foodborne illness frequent? Or is it rare? Or is it both?

- Example of Egypt
  - Population: approximately 120 million population
  - 3 servings per day (or is it 6 including snacks?)
  - 365 days per year, 3650 days per decade, 8 decades per life
    - 120,000,000 x 3 x 3650 x 8 = 10,500,000,000,000 meals
  - That is **10.5 trillion meals** in current Egyptian lifetimes
- On a per-serving basis, foodborne illness is **rare**.
- At a population-level, foodborne illness is very **frequent**.
- If each serving has a 1 in a million probability of illness, that would lead to 10,500,000 illnesses in current Egyptian lifetimes.
- If each serving has a 1 in a billion probability of death, that would lead to 10,500 deaths in current Egyptian lifetimes.

The Qualitative to Quantitative Continuum of Risk Assessment

- Narrative
- Narrative with Risky Terminology
- Structured Qualitative
- Semi-Quantitative
  - Labels and Combinatorial Rules
  - Scoring Systems
- Quantitative
  - Deterministic
  - Probabilistic

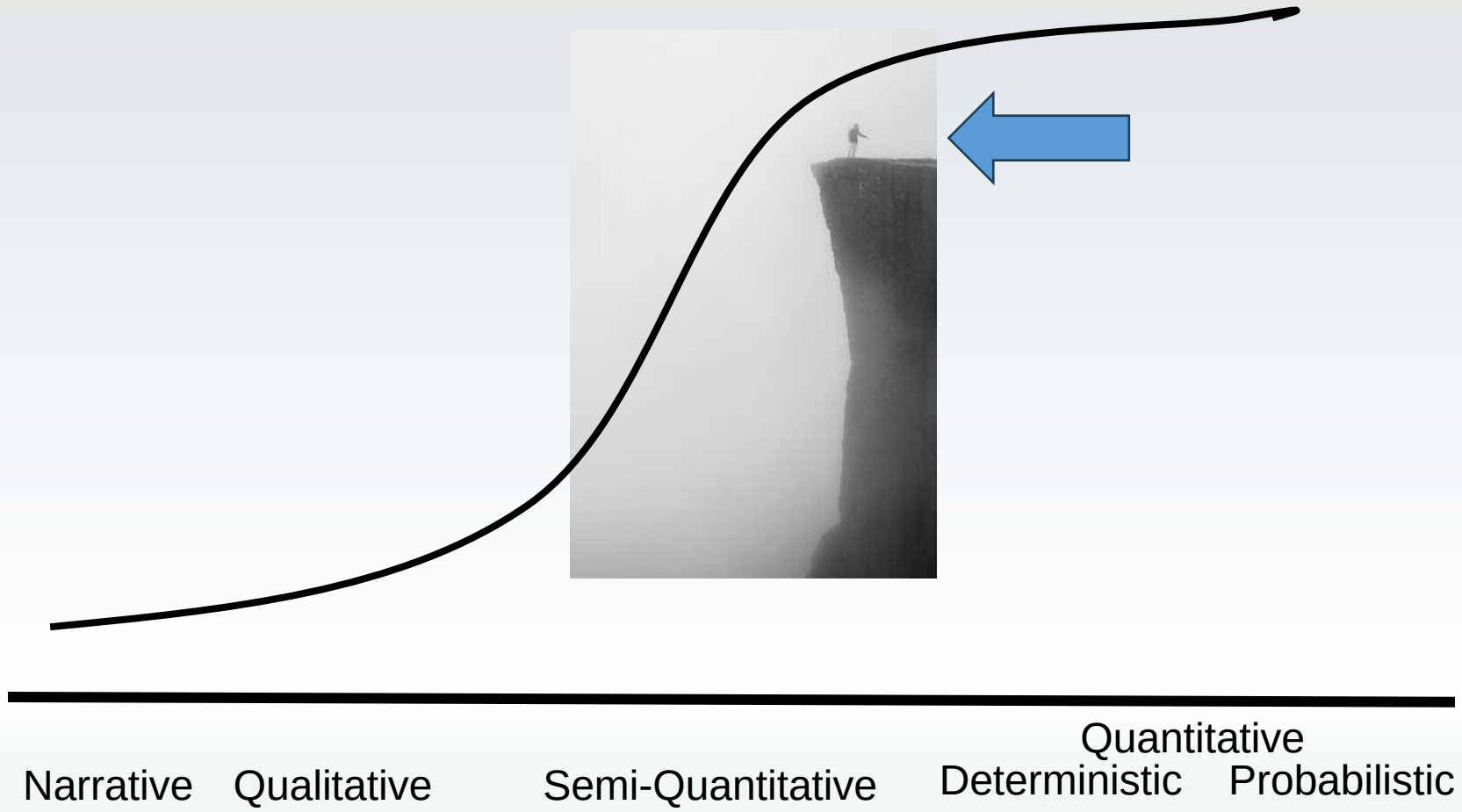
An everyday question …

- A physical hazard (broken glass) is known to occur at a rate of 1 in every million food packages.
- An imperfect test exists for the hazard.
  - The test will be “positive” and detect the hazard 99% of the time.
  - When the hazard is absent, the test will be “negative” 99% of the time.
- A test is conducted at random on one food package.
  - The test gives a “positive” result.
- Question: What is the probability that the food package has the defect?

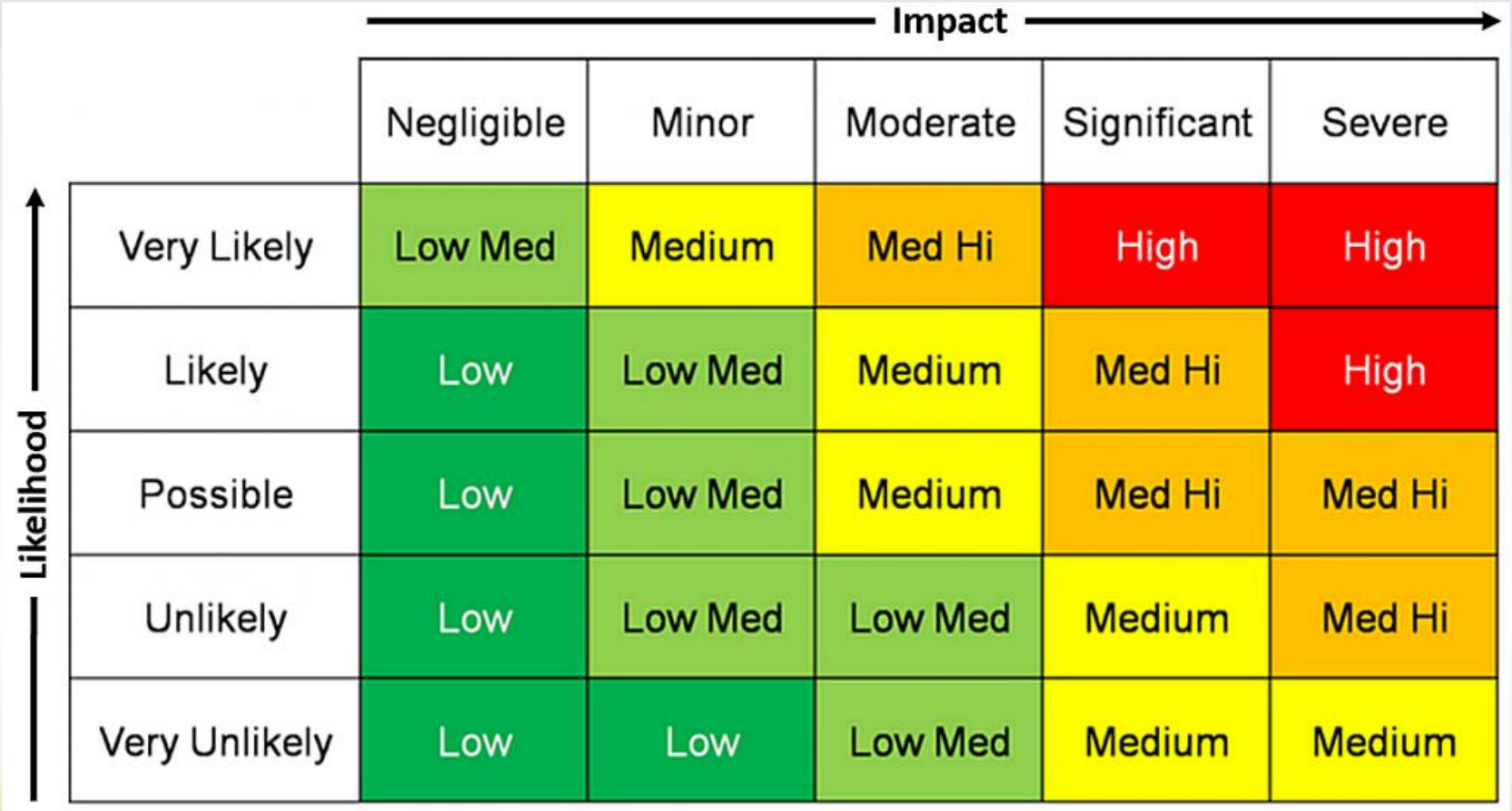
Your best guess

- What is the probability that the food package has the hazard?
  a) 1%
  b) 99%
  c) Approximately 1 chance in 10,000
  d) Approximately 1 chance in 1 million

Quality of Conclusions



Qualitative Risk Matrix



Likelihood \ Impact	Negligible	Minor	Moderate	Significant	Severe
Very Likely	Low Med	Medium	Med Hi	High	High
Likely	Low	Low Med	Medium	Med Hi	High
Possible	Low	Low Med	Medium	Med Hi	Med Hi
Unlikely	Low	Low Med	Low Med	Medium	Med Hi
Very Unlikely	Low	Low	Low Med	Medium	Medium

Semi-Quantitative Risk Matrix

This scoring system attempts to represents the basic concept that the risk is the product (i.e., multiplication) of likelihood and consequences.

		Consequence				
		Negligible 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Likelihood	5 Almost certain	Moderate 5	High 10	Extreme 15	Extreme 20	Extreme 25
	4 Likely	Moderate 4	High 8	High 12	Extreme 16	Extreme 20
	3 Possible	Low 3	Moderate 6	High 9	High 12	Extreme 15
	2 Unlikely	Low 2	Moderate 4	Moderate 6	High 8	High 10
	1 Rare	Low 1	Low 2	Low 3	Moderate 4	Moderate 5

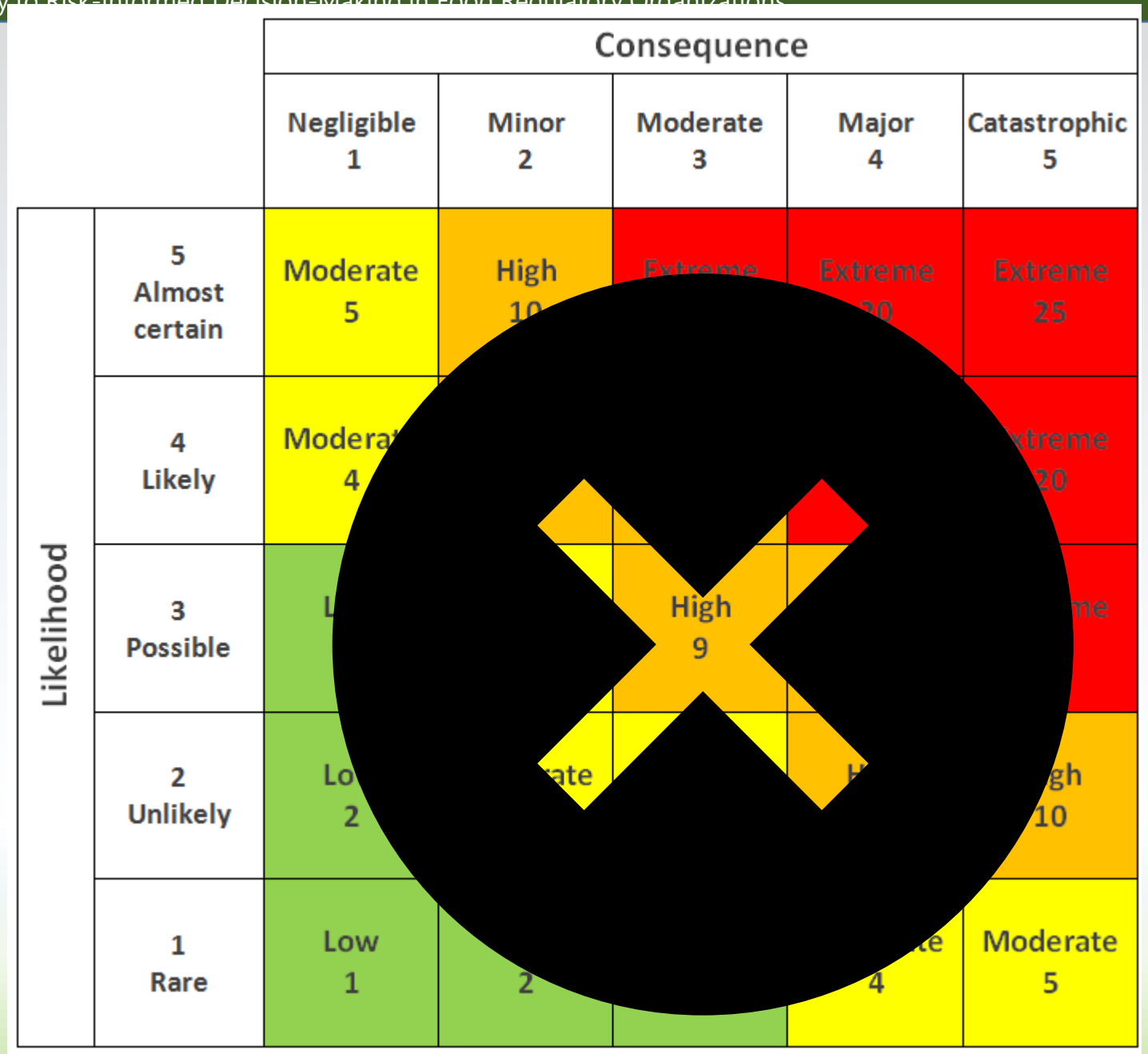
Semi-Quantitative Risk Matrix

While we often say:

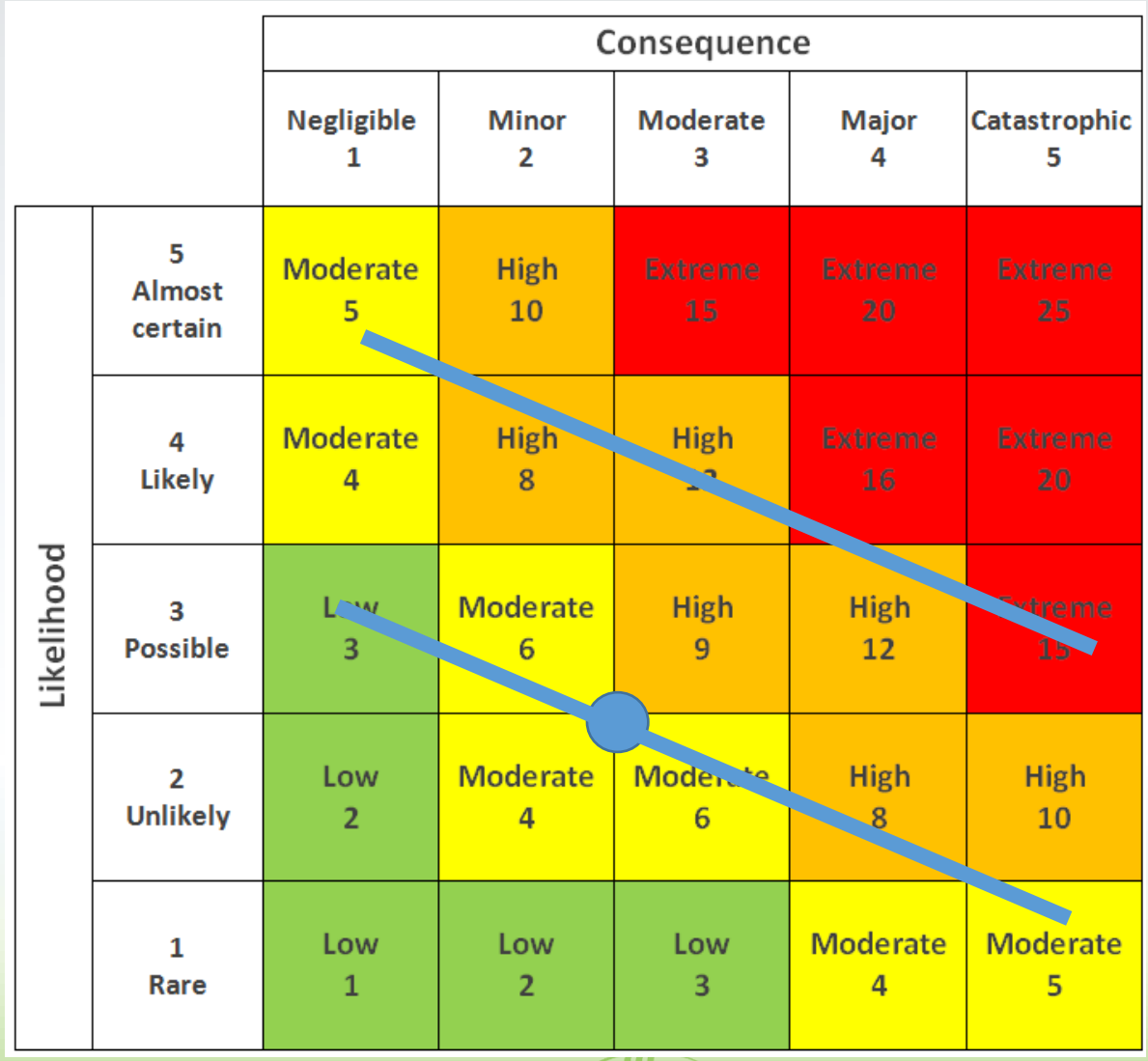
R = Probability * Consequence

in this case, the use of multiplication is not correct.

Detail: the scores are logarithmic, so the correct operation is addition!



Usually, risk is not a 'dot', it's a line (or multiple lines)



Foundational Aspects of Risk-Informed Decision-Making in a Regulatory Context

Risk-Based: what might that mean?

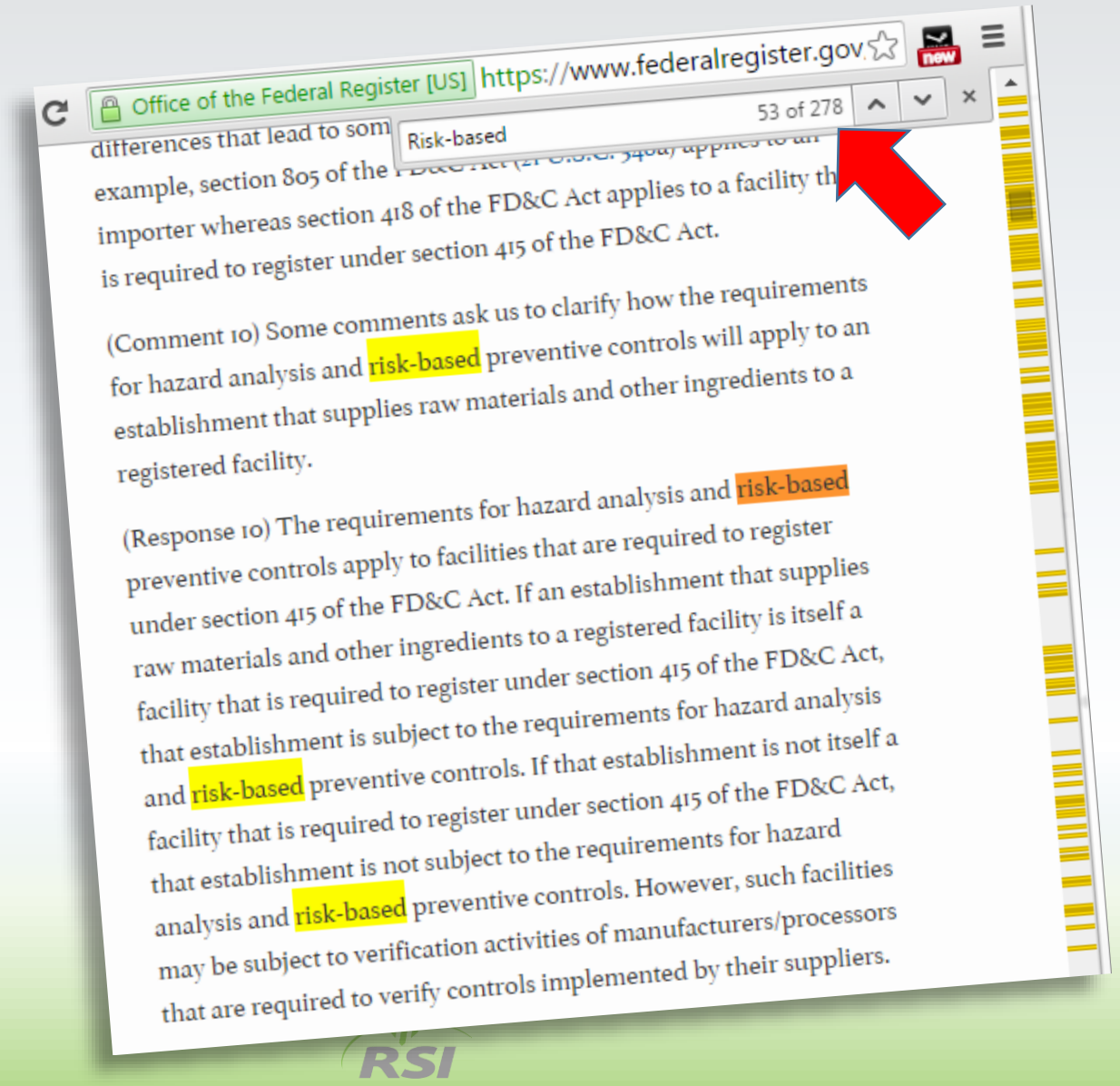
Risk Assessment: Key Elements

- Evidence is *processed* in order to generate statements of probability of individual events which are combined to determine the probability of an adverse outcome of interest.
- The *primary value-added feature* is in the inference of the probability of adverse outcomes by *appropriately combining* a formal representation of the risk generating system with the *rules of calculating probability*.

"Risk-Based"

- Widely used to describe regulatory systems, yet it is not formally defined.
- The term has become a "badge of legitimacy" for regulators and the controls and activities that they employ.

A Pandemic of "Risk-Based," but it remains undefined!



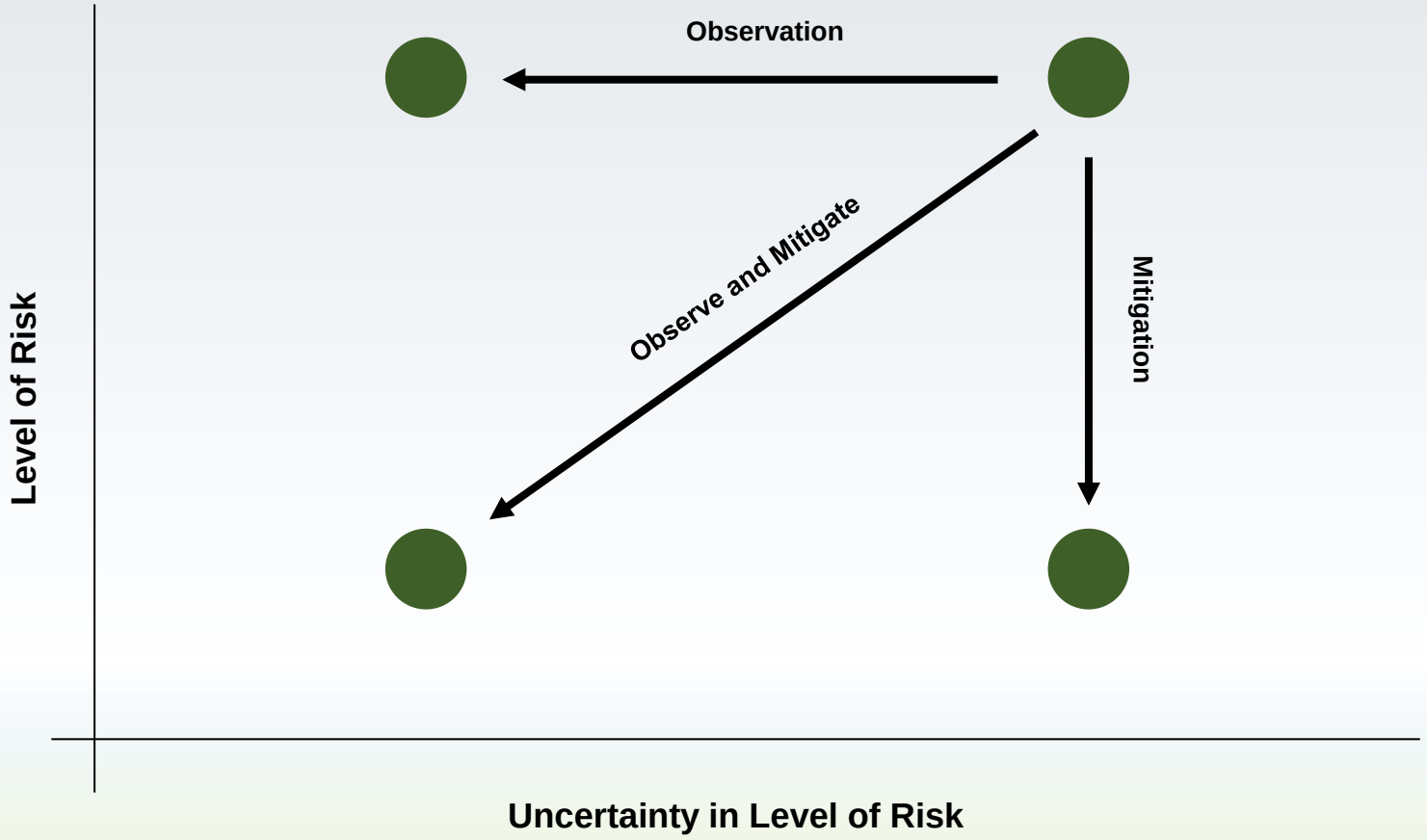
Risk-Based

- It is typically associated with:
  - the principle of proportionality in the application of risk control measures
  - acknowledgement that zero risk is not a realistic goal
  - that the probability of harm, rather than the mere possibility, will be duly considered
- The unstated underlying quality is that decisions are made based on some combination of:
  - the level of risk
  - the level of risk reduction
  - cost-effective risk reduction

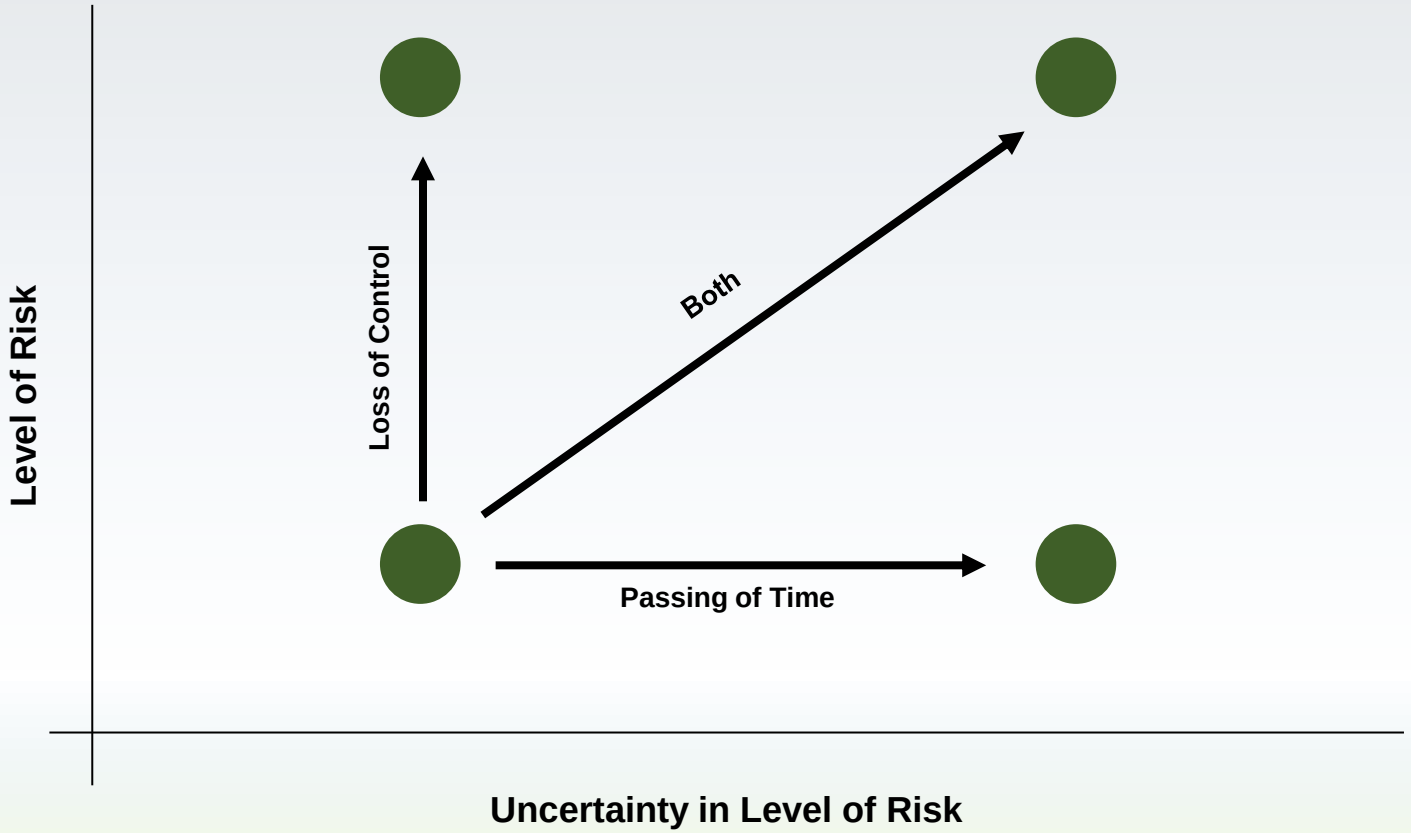
Two Outcomes that Could be Described as 'Risk-Based'

- Reduction in the number and the severity of the adverse outcomes.
  - ➢ Less Risk!
- Increase or maintenance of the level of certainty of the level of risk at which the systems are believed to be operating.
  - ➢ Less Uncertainty in the Level of Risk!
- These are two very different goals with different tools and means of measurement.

Reducing Uncertainty and/or Risk



After the Inspection



"Risk-Based" Operates at 4 Levels (or more)

- Level 1: Why do we do what we do? Why do we not do what we don't do. Who should do what? What will "risk-based" mean for us?
- Level 2: What types of domestic hazards and foods should we concentrate on? What types of imports should we be sampling?
- Level 3: How frequently should we inspect Company X versus Company Y. When doing the inspection, what should we pay most attention to?
- Level 4: When an inspector find a mis-calibrated thermometer during an inspection of a milk pasteurization plant, what should he/she do?

Foundational Aspects of Risk-Informed Decision-Making in a Regulatory Context

Foundational Elements Underlying Risk-Informed Decision-Making

Components of Risk-Informed Decision Making

1. Foundational Elements
   - Core matters of Policy as it relates to public risk and its management
   - Ideally, these would be determined prior to invoking day-to-day (or year-to-year) Risk-Informed Decision Making processes.
2. Risk Management Processes
3. Risk Assessment Processes

Foundational Elements of Public Risk Management

1. Risk Management Principles
2. Inventory of Public Harms within Mandate
3. Measurement Scales for Public Consequences
4. Common Principles of Risk Assessment
5. Risk Control Inventory
6. Detailed Causal Analysis of Risk Controls
7. Integration of Parallel Analyses of Costs and Effectiveness of Risk Controls

Risk Management Principles (2)

- Risk Management is driven by the pursuit of many virtues.
- But which is the highest god?
  - The God of Risk. Action: Go where the risk is
    - Sub-God of Individual Risk: Go where the largest individual risk is
    - Sub-God of Population Risk: Go where the highest population risk is
  - The God of Risk Reduction: Go where the risk can be reduced.
  - The God of Cost-Effective Risk Reduction: Maximize overall risk reduction within a constrained budget.
  - The God of Risk Thresholds: reduce risk to the threshold of risk tolerability
  - The God of Consistency: treat everyone equally, consistently, or fairly
  - The God of Knowledge: Gather information about risks so that questions can be knowledgeably answered.

Foundational Aspects of Risk-Informed Decision-Making in a Regulatory Context

Issues in Risk Measurement

Measurement Scales for Public Consequences

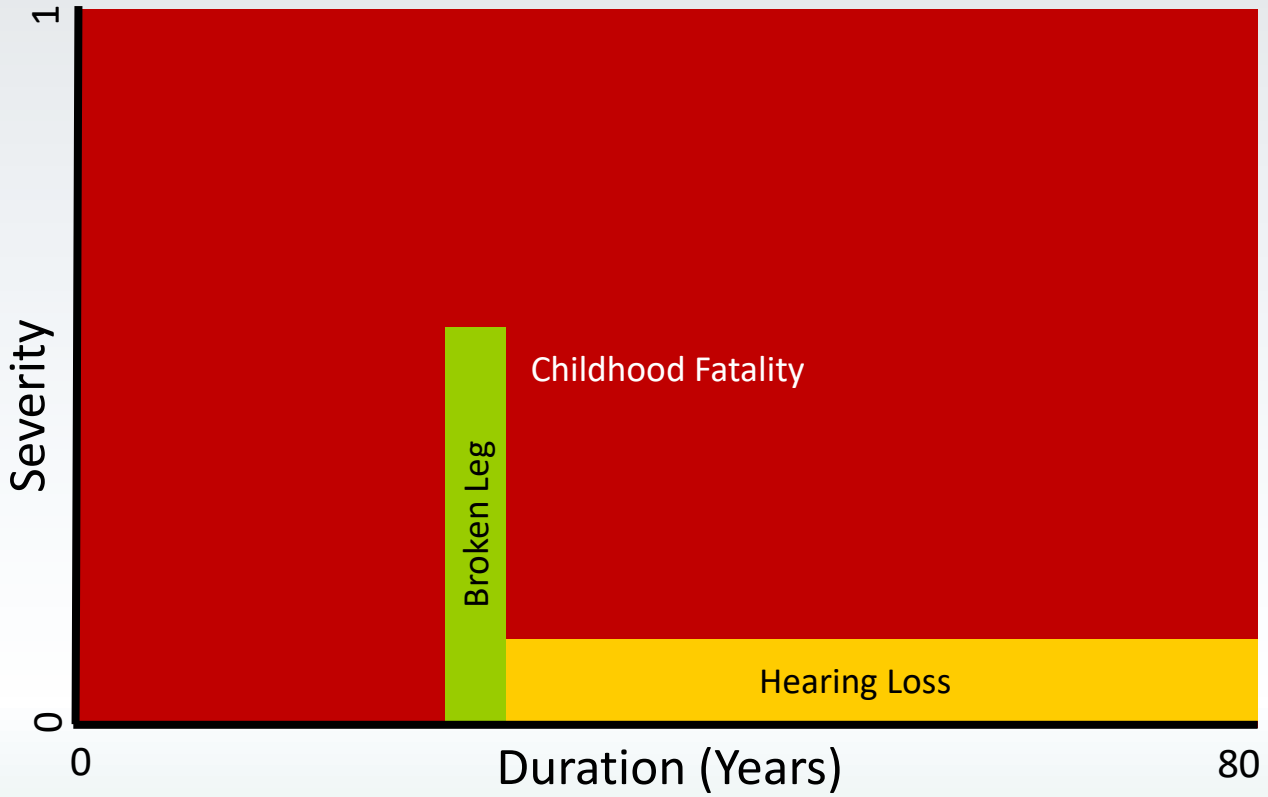
- What are the appropriate means to measure public consequences?
  - What other forms of harm will be included and how will they be measured?
  - How will the organization address social inequity in exposure to losses?
- What are inappropriate means to measure public consequences?
  - E.g., Is it appropriate to place a higher value on 200 people affected all at once versus 200 people affected separately and individually?
  - Is it appropriate to measure consequences that range from trivial to catastrophic on a scale of 1 to 5 with the implicit expectation that 4 is twice as bad as 2, even if 4 is really 10,000 times worse than 2.
- How will diverse consequences be compared on a common scale?

You Can't Compare Apples and Oranges! (Actually, you can!)

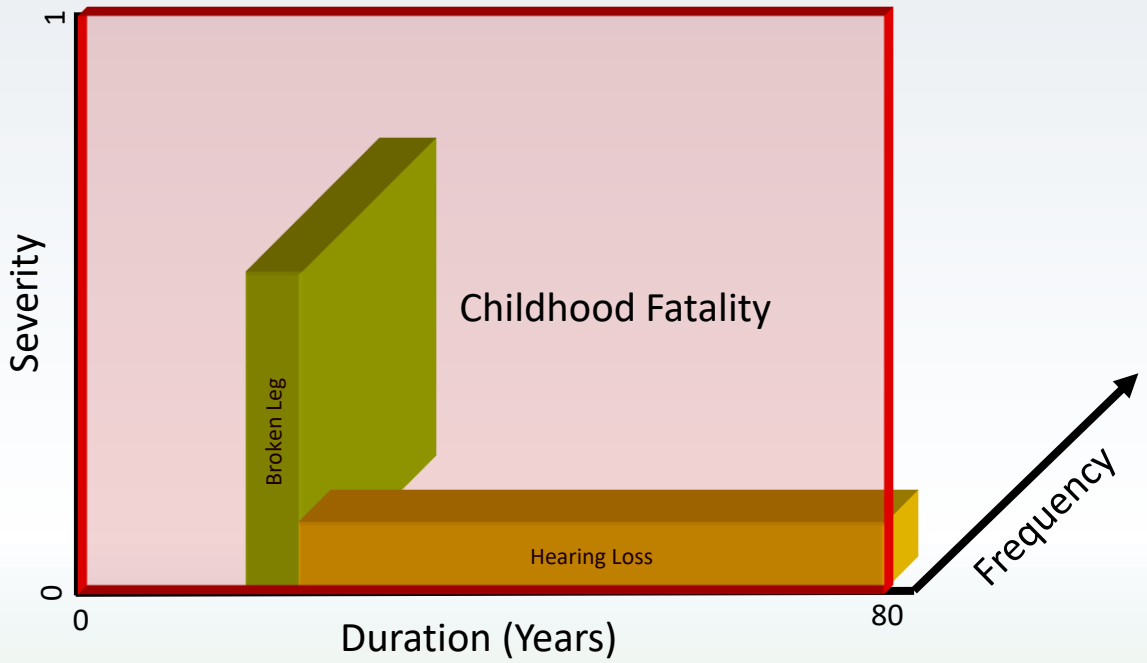
- A common accusation that has never been true!
- Comparing apples and oranges is both common and easy!
- Comparisons need to be well thought out and mathematically defensible

- How can we defend not formally considering Severity?

Disability Adjusted Life-Years (DALY)



Incorporating Frequency



Inventory of Public Consequences within Mandate

- What are all of the consequences to the public, or the public interest, that must be considered in fulfilling its mandate.
- What are all the sources of these consequences to the public?
- What role does the public benefit of reduced costs for retailers play in risk-based decision-making about legal metrology?
- Is knowledge of the levels of risk a public good in itself?

Foundational Aspects of Risk-Informed Decision-Making in a Regulatory Context

Risk Controls and Cost-Effective Resource Allocation

Risk Control Inventory

- What are all of the ways that your organization can influence the level of public risk with respect to any of the identified consequences?
- From the most proactive to the most reactive …
- From the long-term to the immediate …

Public Risk Control Taxonomy – CFIA

Risk Control:
an action intended to reduce the probability and/or severity of harm, or to reduce the public or organizational

Programme design and implementation	International and Intergovernmental Co-operation	Preventative Communications	Permissions	Compliance Verification	Surveillance	Response
Science and information Gathering	Multi-lateral and bi-lateral agreements	Public Education Materials and Events	Specific Risk Assessments and Authorizations	Domestic Establishment System Audits	Broad and Targeted Surveillance	Enforcement
Regulatory and Guideline Development	Country-level evaluations	Compliance Promotion	Licensing	Facility Inspection	Laboratory analysis (surveillance)	Investigation and Recall
Program Design for Existing Authorities	Participation in International Bodies		Permitting	Product Inspection & Sampling		Animal Disease, Feed, Plant Pest Response and Controls
Program Review and Evaluation	Cooperation within Canada		Accreditation of Third Parties	Laboratory Analysis (compliance)		Agricultural Input controls
Emergency Preparedness			Export Certification to Import Requirements	Consignment-level Import Activities		Emergency Communications
			Laboratory Analysis (certification)	Humane Treatment		Post-event Market Access Recovery
				Conveyance Monitoring		Laboratory Analysis (response)
				Animal Identification		

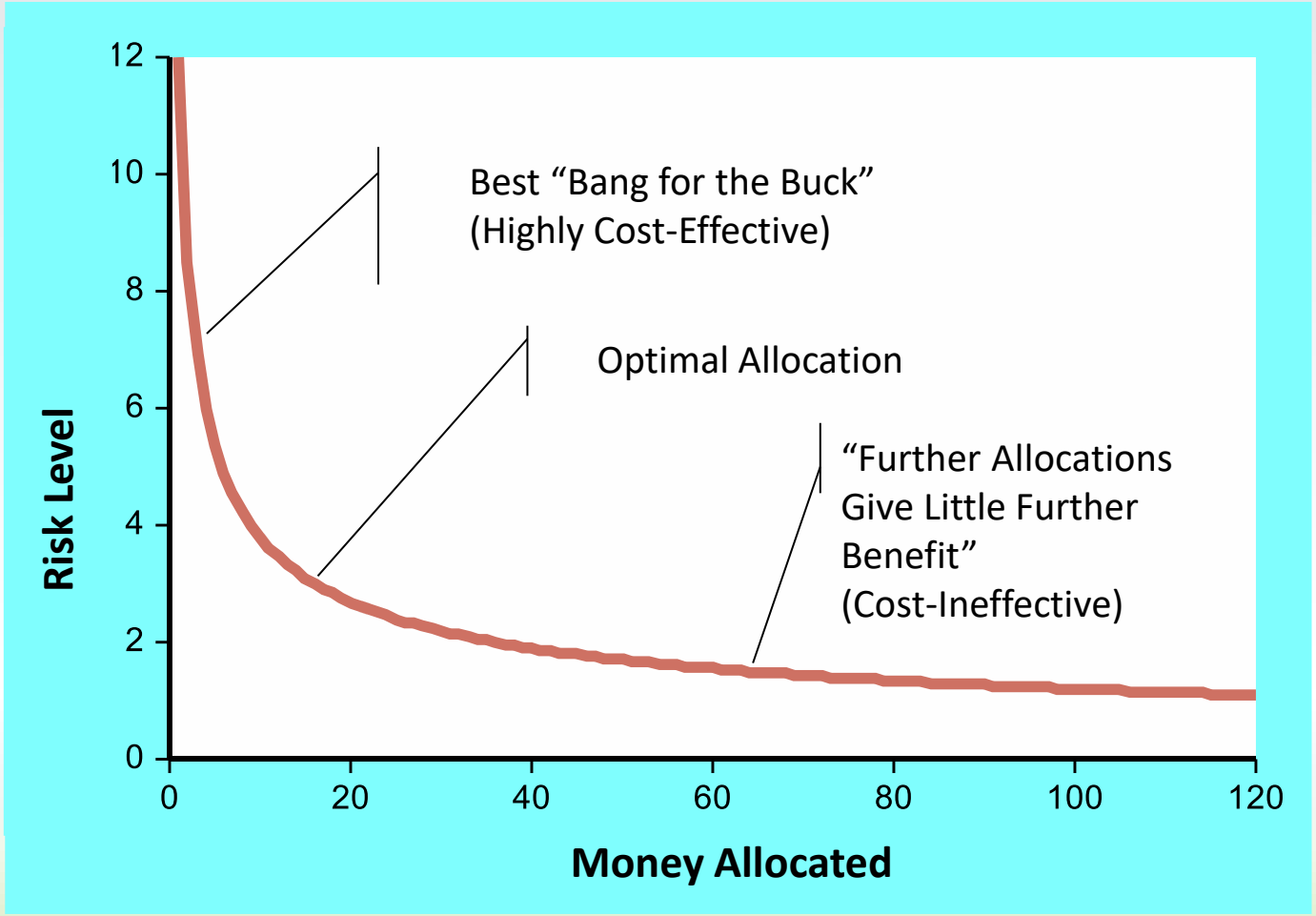
Detailed Causal Analysis of Risk Controls

- What is the overall system of controls that ensures an acceptable level of compliance within sectors with mandatory inspections?
- What is the causal relationship between a given investment and a change in the level of public risk, given the rest of the system of controls?
- What fraction of the variability in risk is “inspectable risk”?
- What fraction of the variability in risk in “inspectable and modifiable”?
- What fraction of impact is risk reduction versus uncertainty reduction?
- Having done an inspection today, what aspect of the measurement system is subject to change over time, how important are these changes, and how quickly does the system change?
  - This is the question behind the question of inspection frequency.

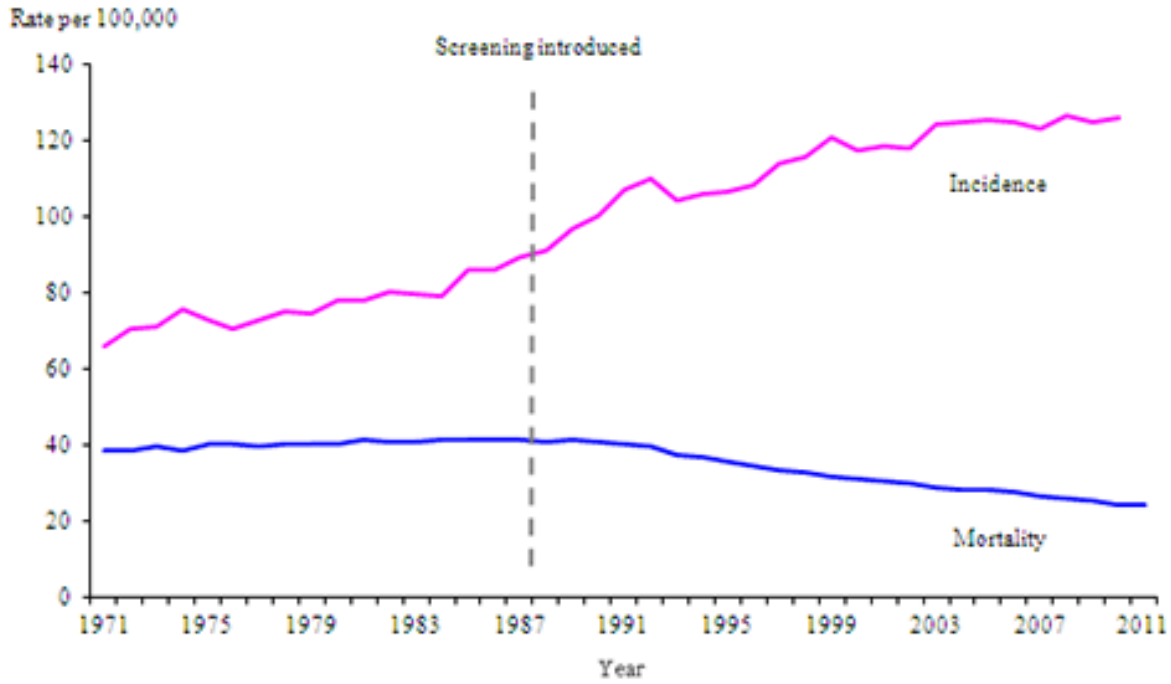
A Central Objective of *Risk-informed* Decision-Support

- To provide an analytical framework in which resource-allocation decisions are maximally *risk-informed*.
- To provide a "starting point" for resource allocations that would theoretically minimize risks of losses given available resources.
  - The theoretical basis is the economic principle of maximizing marginal cost-effectiveness
- With this input, decision-makers adjust the theoretically optimal allocation to reflect many realities and constraints that the decision-support tool does not yet, or could never, include.

Marginal Cost-Effectiveness



Health Care Analogy



Mortality from breast cancer dropped by half after breast screening ("inspections") commenced in the UK, despite rising incidence of breast cancer.

A tumor is non-compliant tissue

- It refuses to adhere to regulatory expectations of cell death and replication

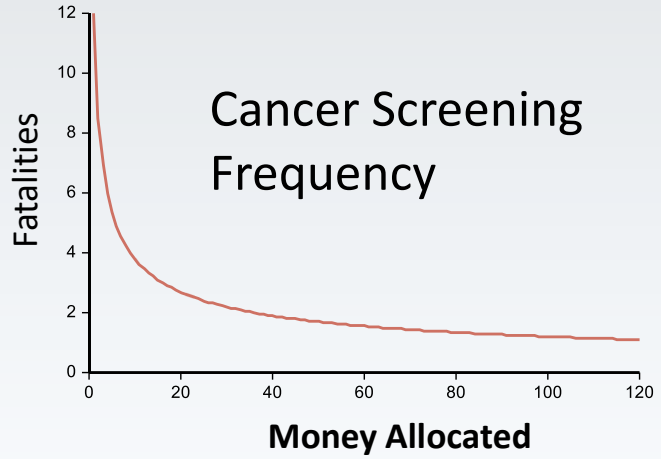
Screening of women over 50 = ***Risk-based*** inspection

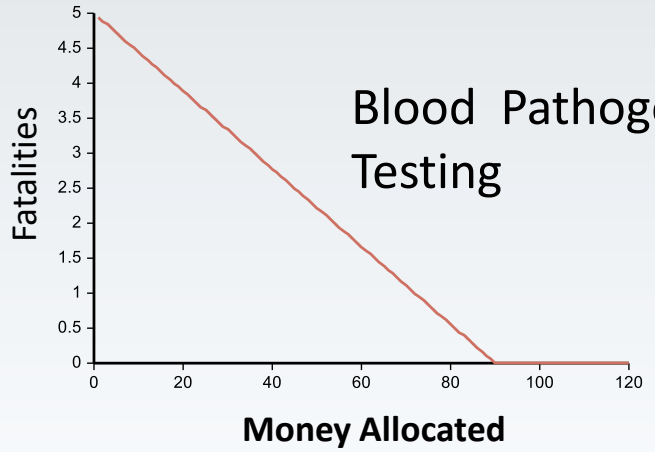
Tumor detection = Detection of non-compliance

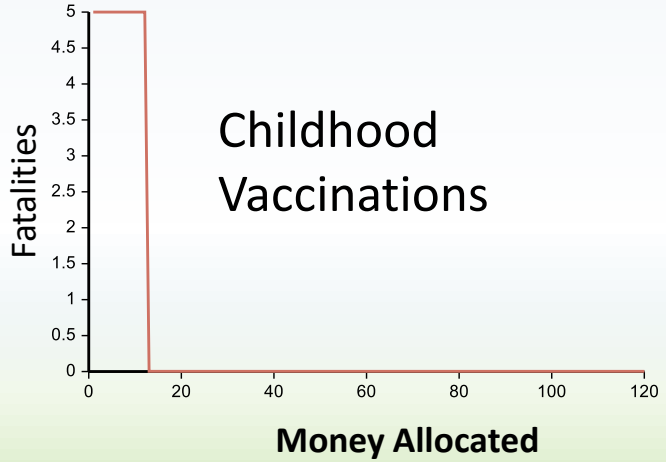
Screening frequency = Inspection frequency

Source: http://www.ons.gov.uk/ons/resources/sbreastcancerimage2010_tcm77-280705.png

Variations on Cost-Effectiveness – Health Care Analogy

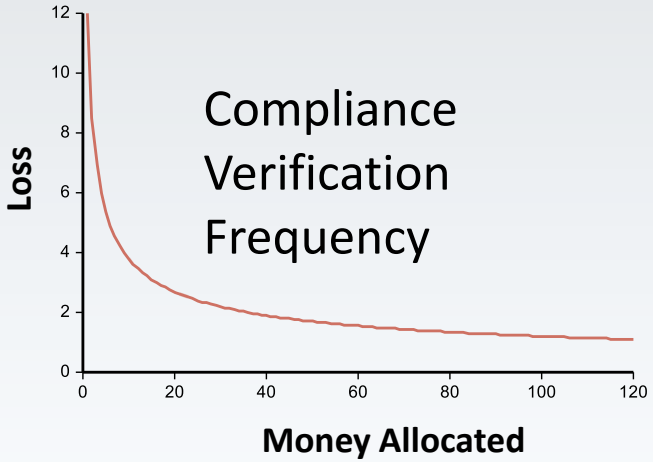


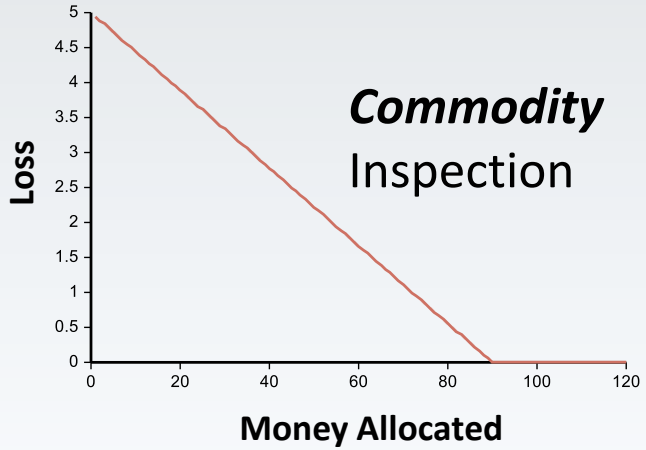


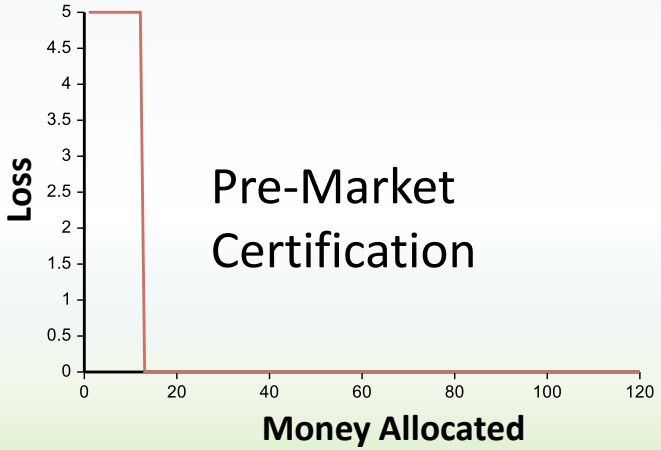


The shape of the curve reflects different patterns in the impact of increasing allocations of funding to risk controls.

Variations on Cost-Effectiveness

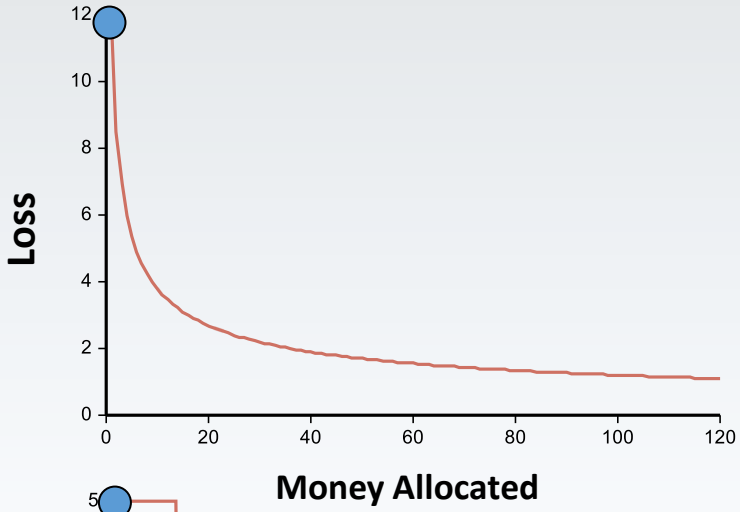


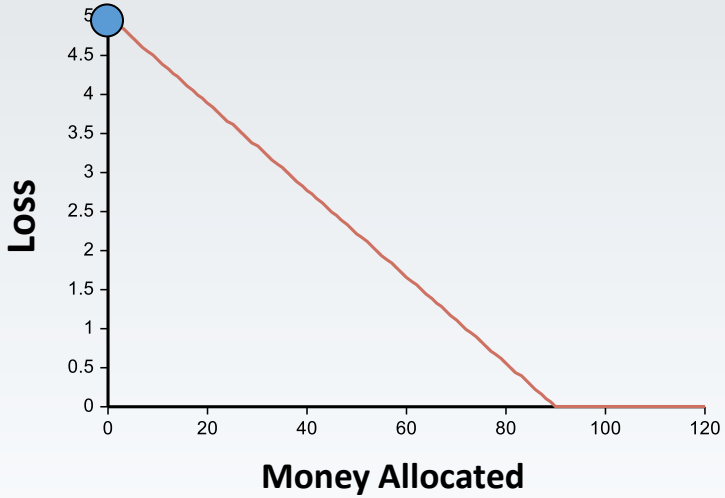


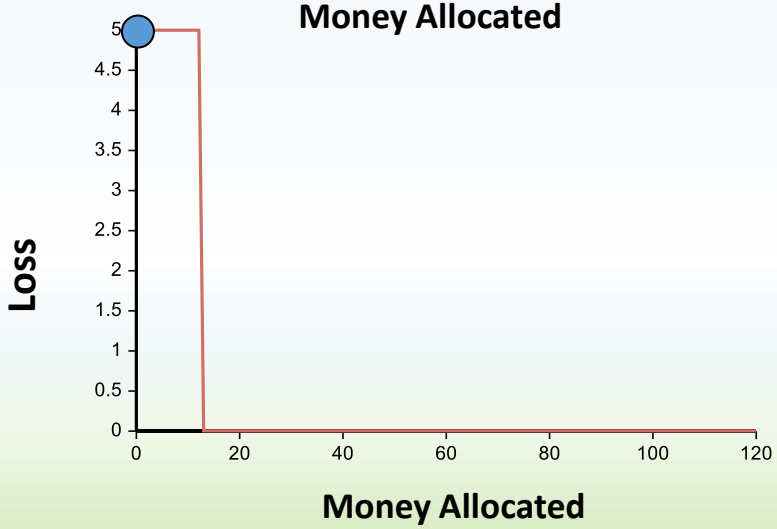


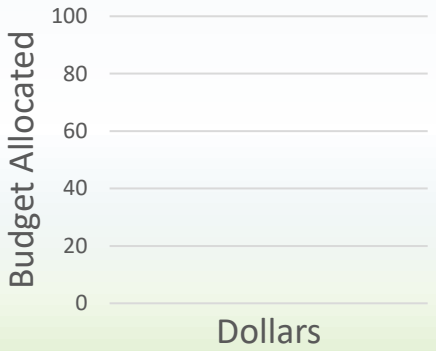
The shape of the curve reflects different patterns in the impact of increasing allocations of funding to risk controls.

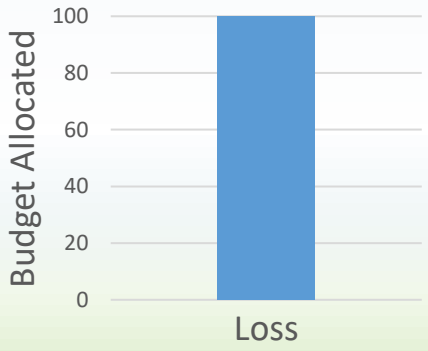
Risk-Informed Resource Allocation through Incremental Cost-Effectiveness Analysis



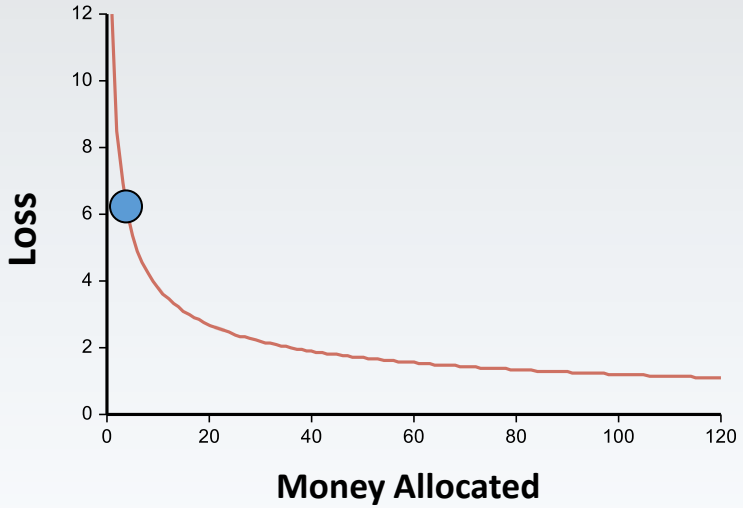


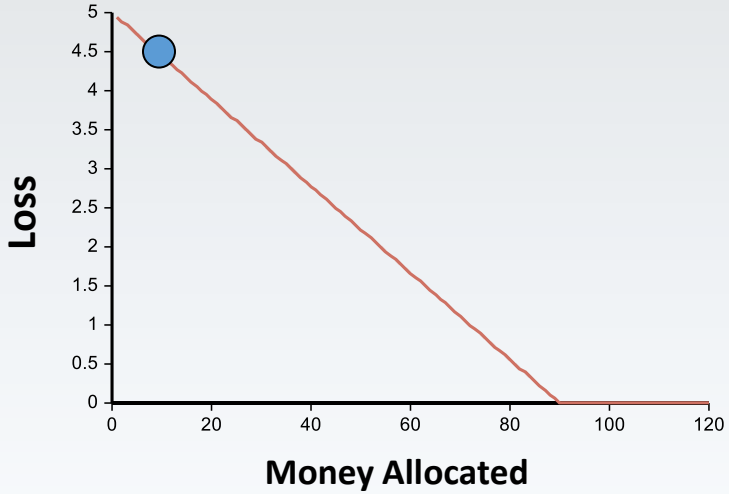


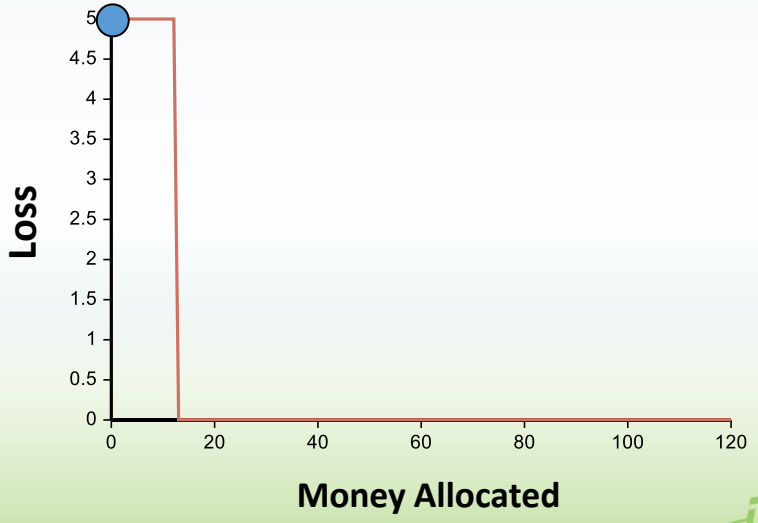


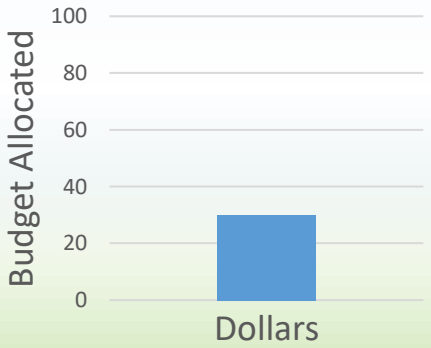


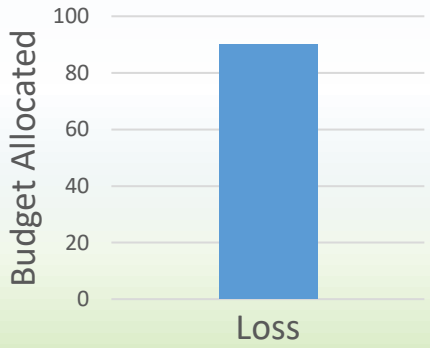
Highly Cost-Effective Investments Made First …



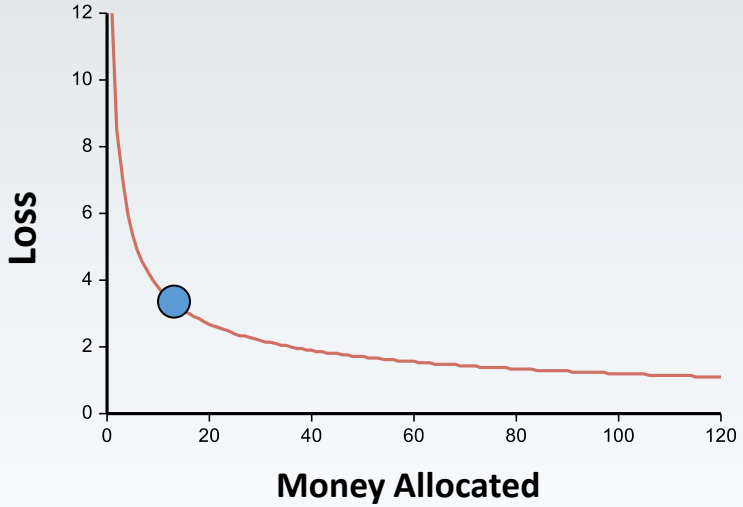


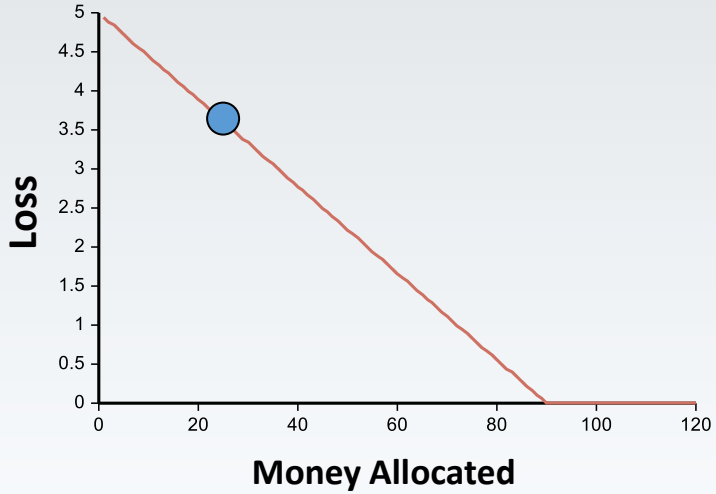


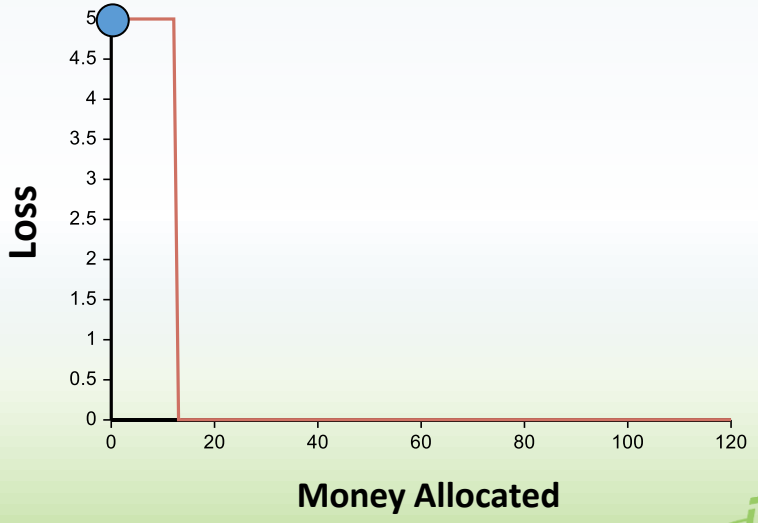


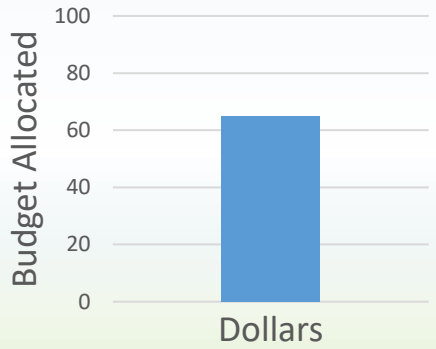


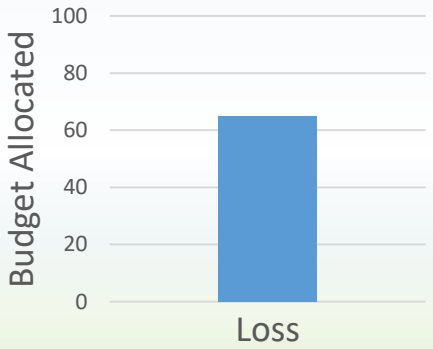
Moderately Cost-Effective Controls Next …



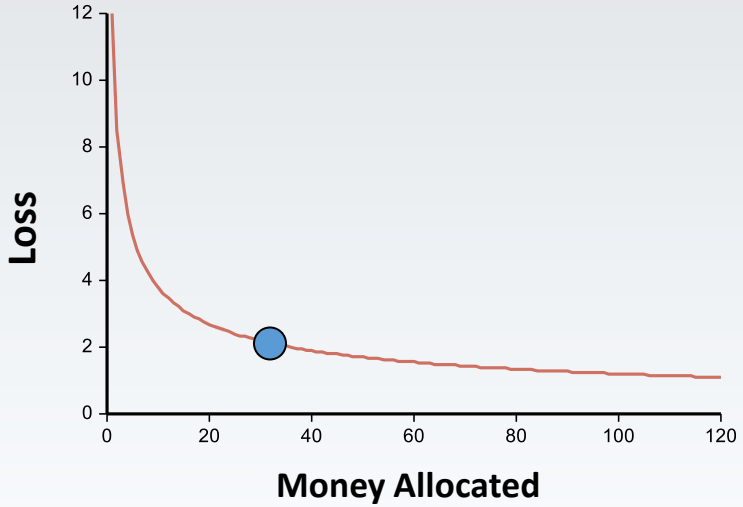


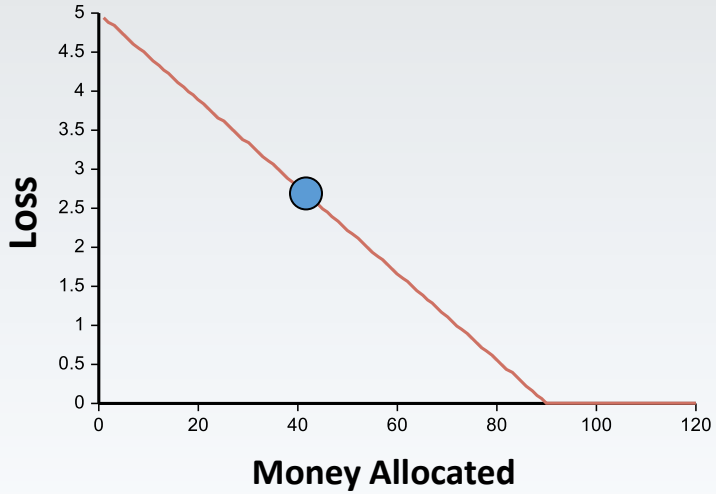


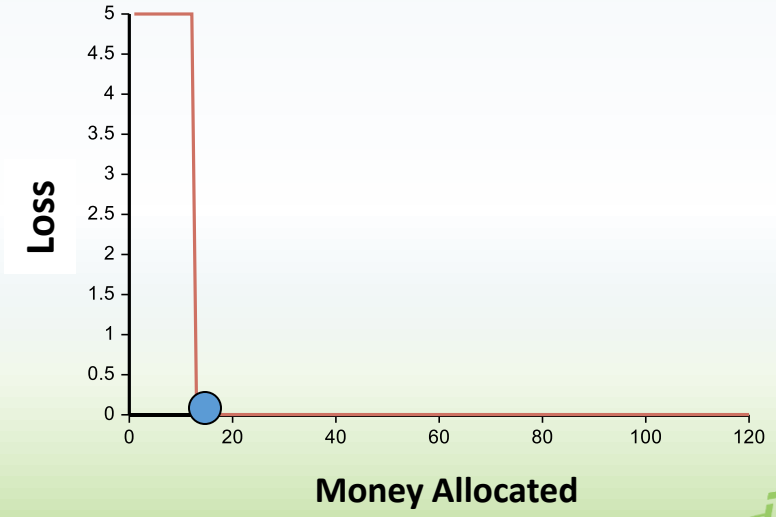


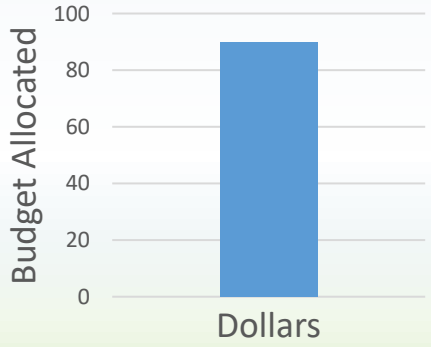


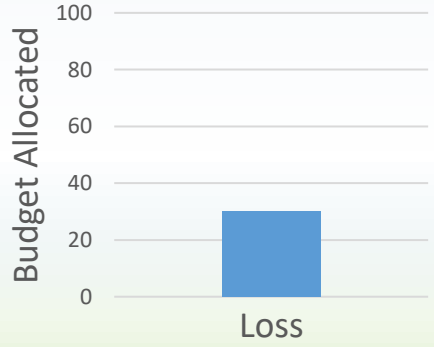
Less Cost-Effective Next …



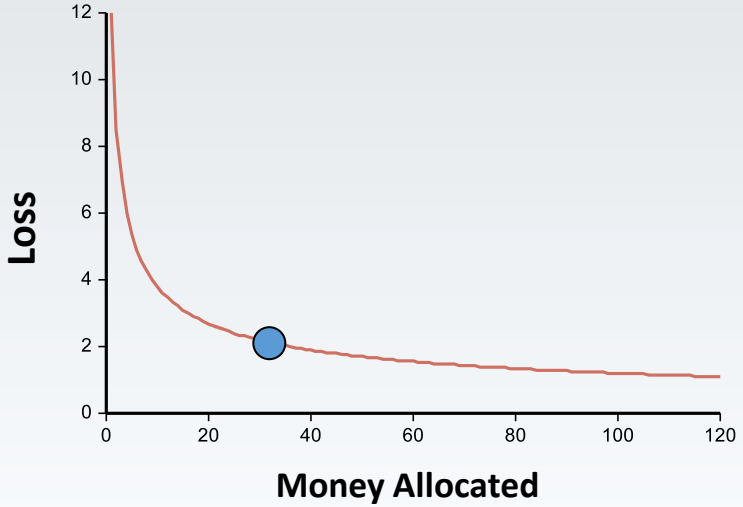


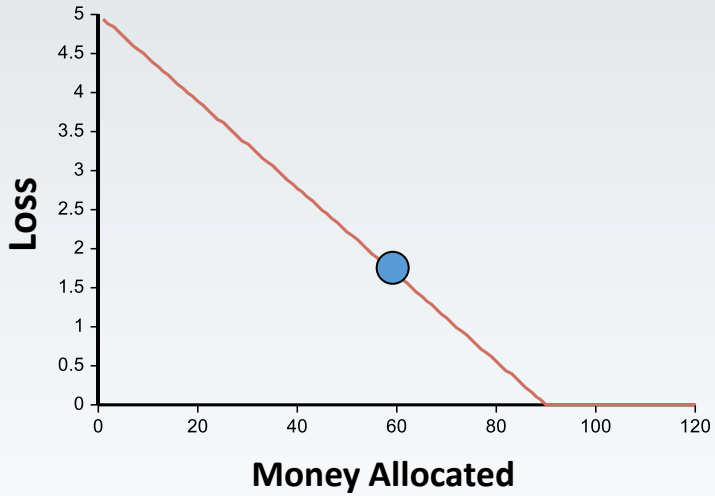


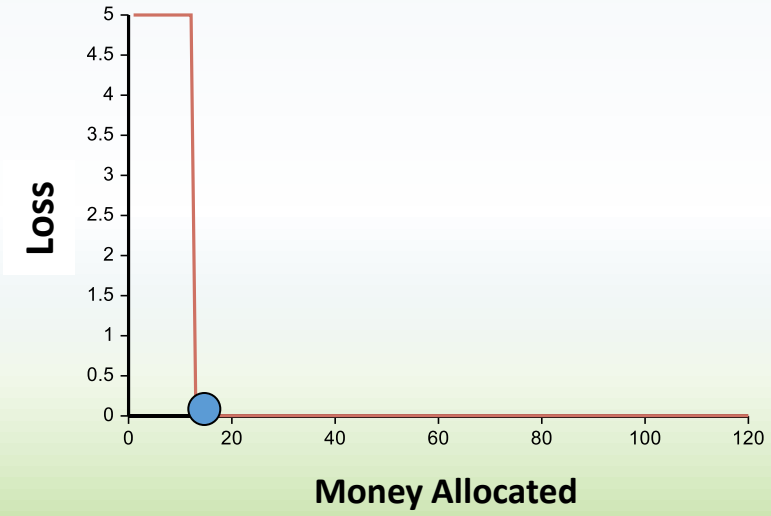


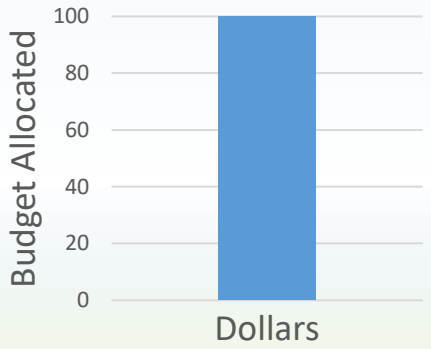


Until Budget Limit is Reached.

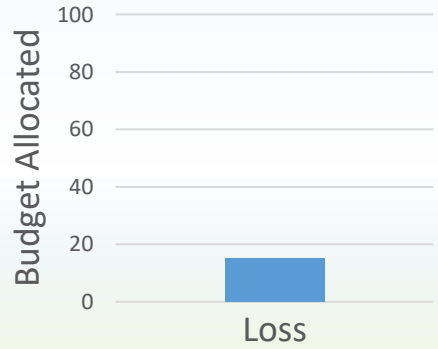








Budget Exhausted



The Journey to Risk-Informed Decision-Making in Food Regulatory Organizations

Summary

To be Fully Risk-informed at all Levels: a Long Journey

- A formal definition of “risk-based” or “risk-informed” doesn’t yet exist
  - Cost-effective risk reduction may be the highest goal
- The key to being fully risk-informed is to achieve harmony across all four levels of decision-making
  - Consistency in quantitative techniques is critical
- Even the most advanced regulators, with decades of experience, are still “climbing the mountain.”