Using Risk to Inform Biodefense Decision-making

Presentation to the Food and Drug Administration Pediatric Ethics Subcommittee

http://wayback.archive-it.org/7993/20170113232609/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM369849.pdf (checked 1 April 2021)

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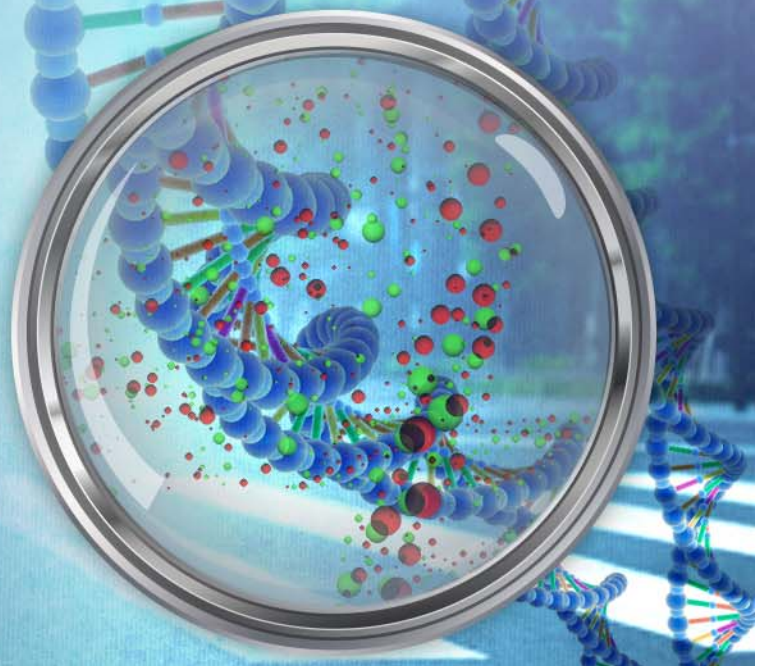
Susan Coller Monarez, Ph. D.
Chief, Threat Characterization and Attribution Branch
Chemical/Biological Defense Division
Science and Technology Directorate

Homeland Security
Science and Technology



DHS Uses Risk to Inform Biodefense Activities

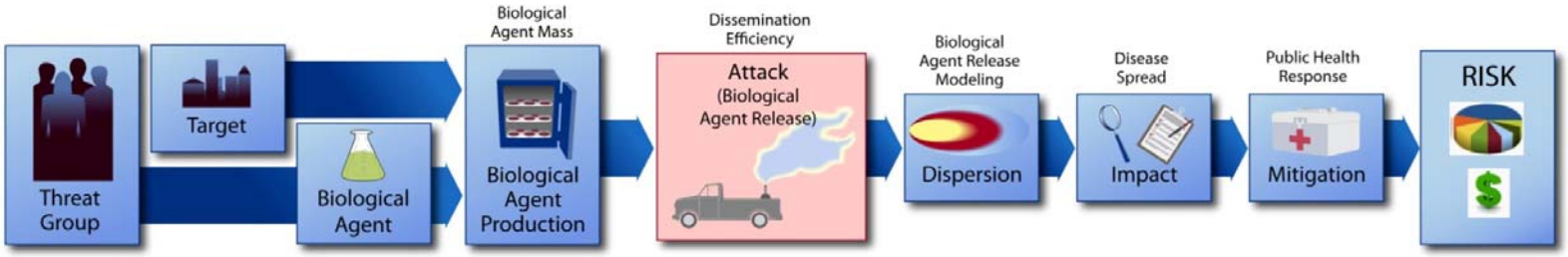
Overall goal: Use scientific and intelligence-derived information to develop Risk Assessments to support operational preparedness, response and recovery strategies and activities

Why Risk Assessment?

- Frequency **and** severity of adverse events matters to preparedness and response planning
- Risk assessment addresses key questions
  - What should we worry about?
  - How likely is it?
  - How bad could it be?
  - What factors contribute the most to the risk?
- Risk assessment capabilities inform risk management decisions such as:
  - What can be done?
  - How impactful are the different options?

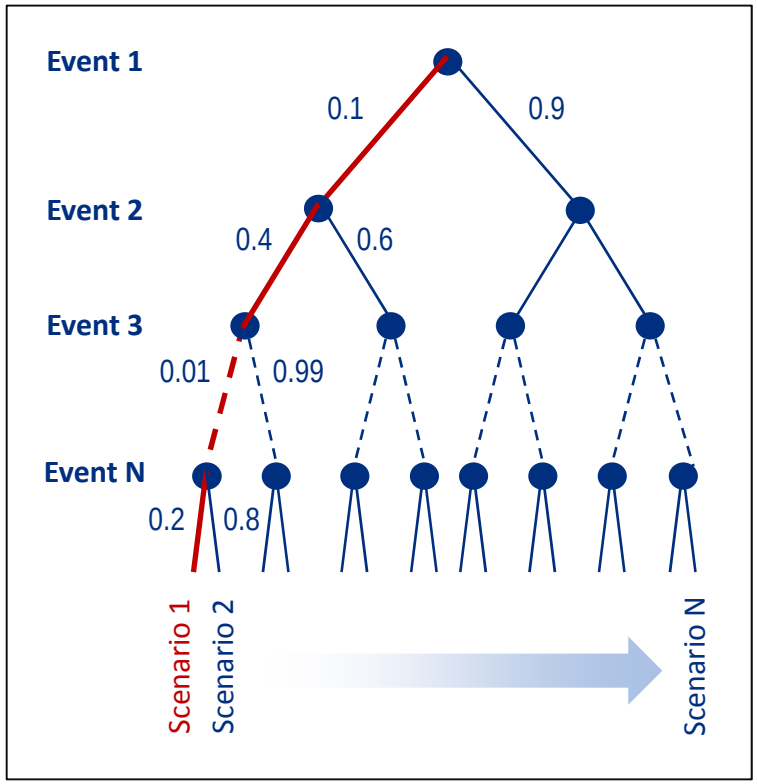
Risk Assessment Methodologies

- Actuarial risk assessment:
  - Use historical data to estimate probability and consequences of adverse events (e.g., car accidents)
- Qualitative risk assessments
  - Likelihood and consequence for events placed upon an arbitrary scale; often based on subject matter expert (SME) opinion (e.g., multi-attribute risk assessment)
- Quantitative risk assessments
  - Use quantitative models and/or judgments to estimate risk for adverse events (e.g., Probabilistic Risk Assessment - PRA)
- Probabilistic risk assessment has been used to estimate bioterrorism risk



Calculating Scenario Probabilities

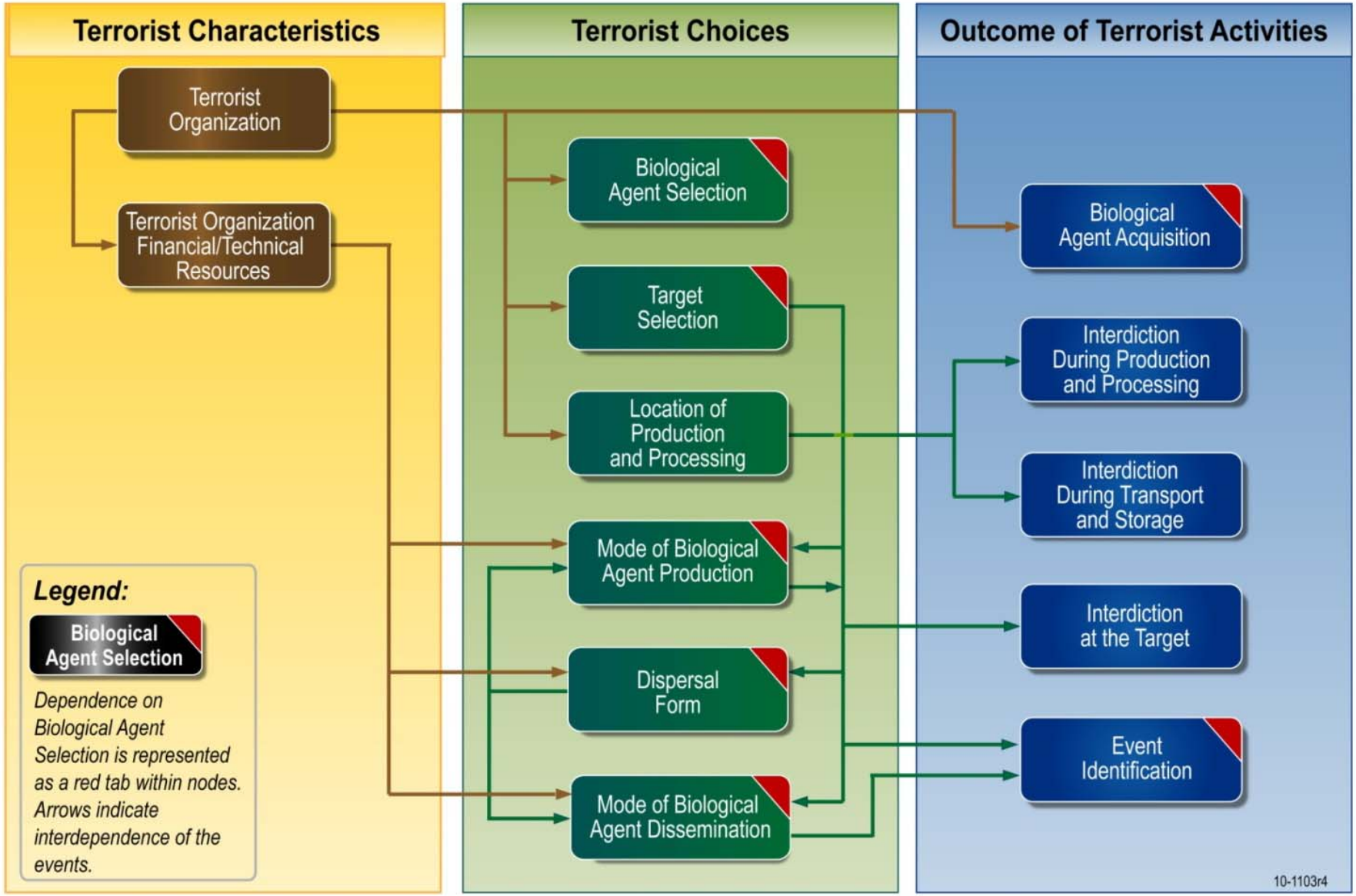
- Calculate probabilities for all scenarios
  - Cumulative probabilities derived from expert elicitation are sampled for each branch



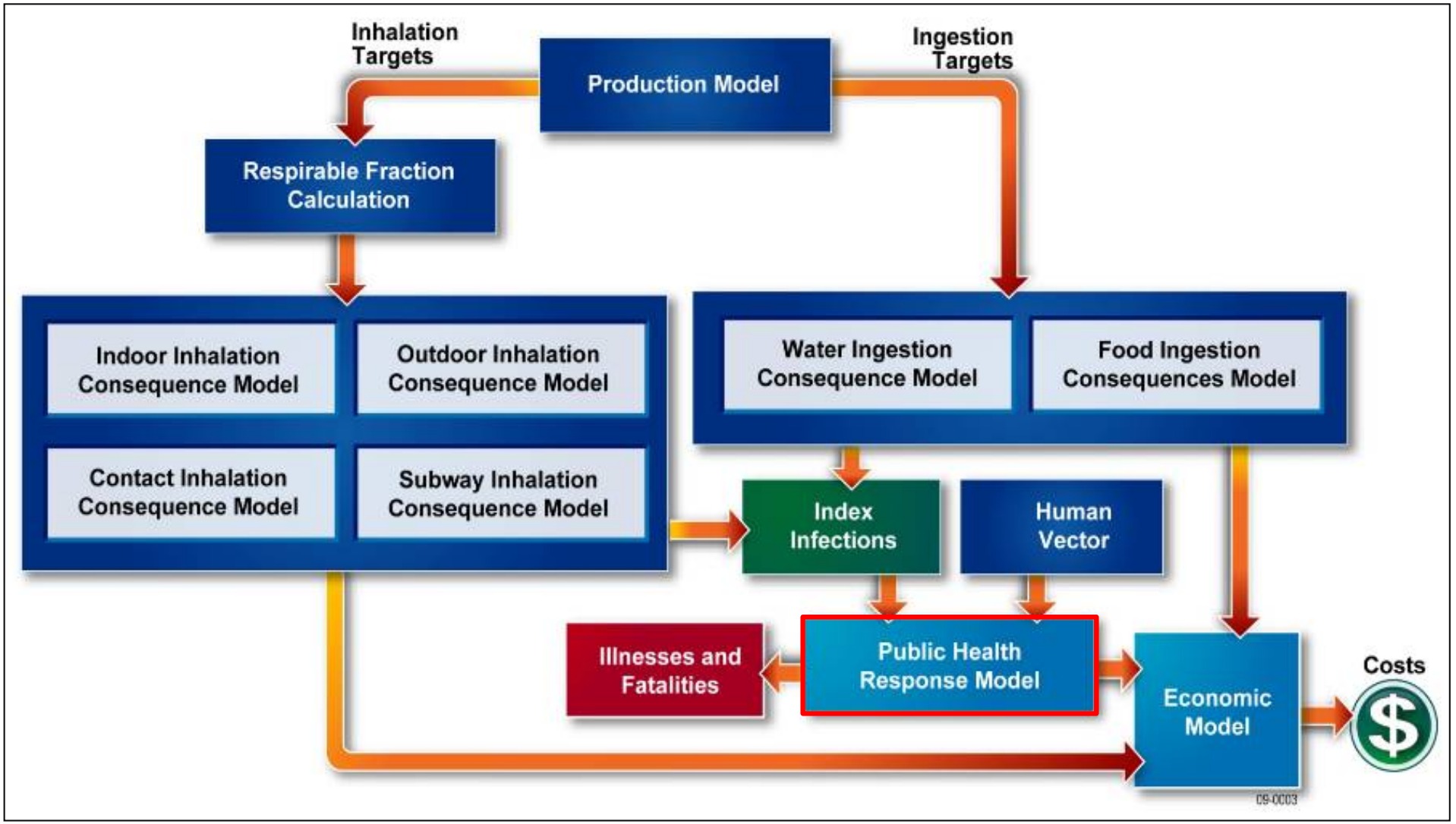
- Probability of Scenario 1
  - Event 1 = 0.1
  - Event 2 = 0.4
  - Event 3 = 0.01
  - Event N = 0.2
  - P = 0.1 x 0.4 x 0.01 x 0.2 = 0.00008
- Risk calculated using all scenarios defined by the event tree

Terrorism Risk Assessment Elements

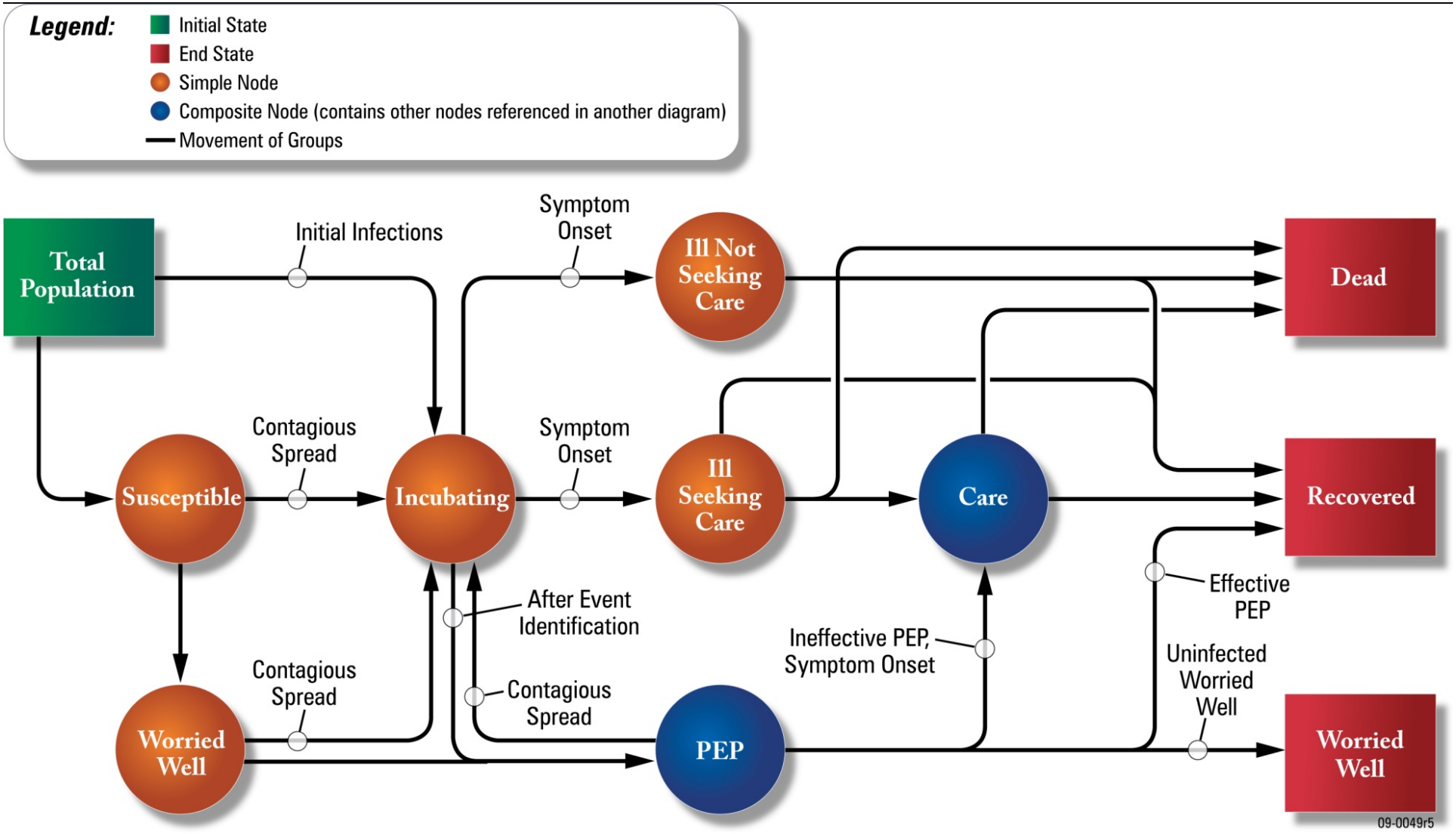
Example of an Bioterrorism Event Tree



Bioterrorism Consequence Models

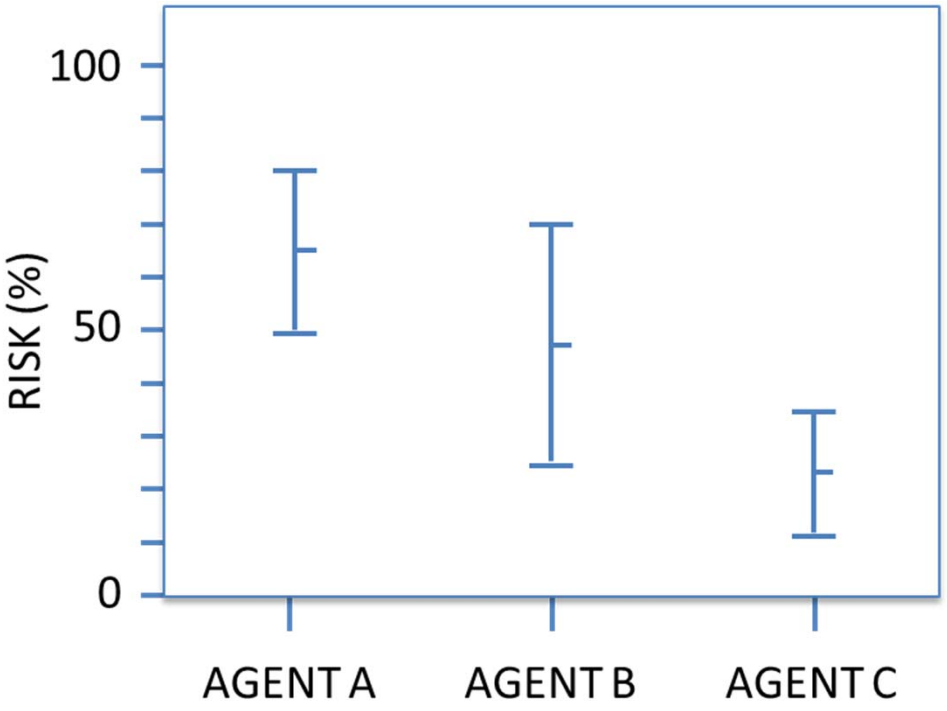


Public Health Response Model

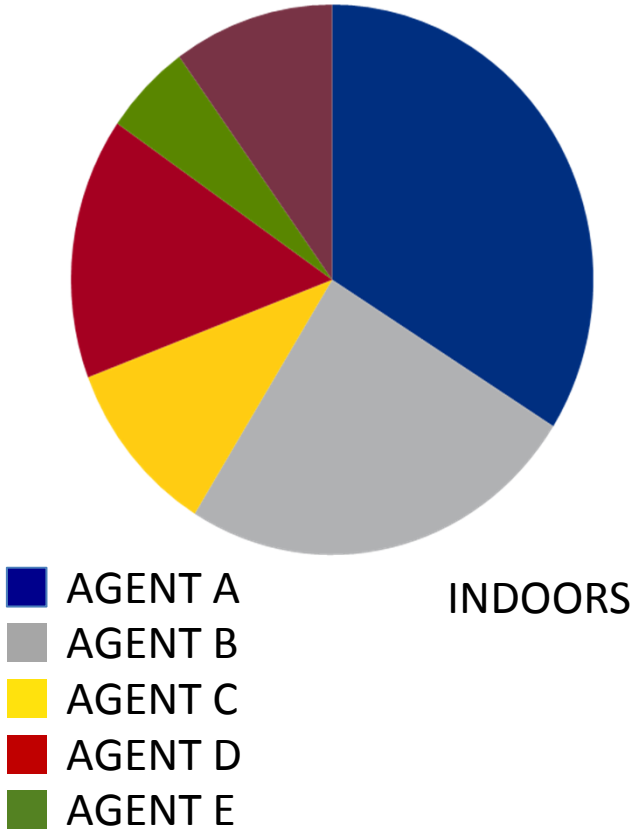


What Should We Worry About?

Example Outputs of the Terrorism Risk Assessment



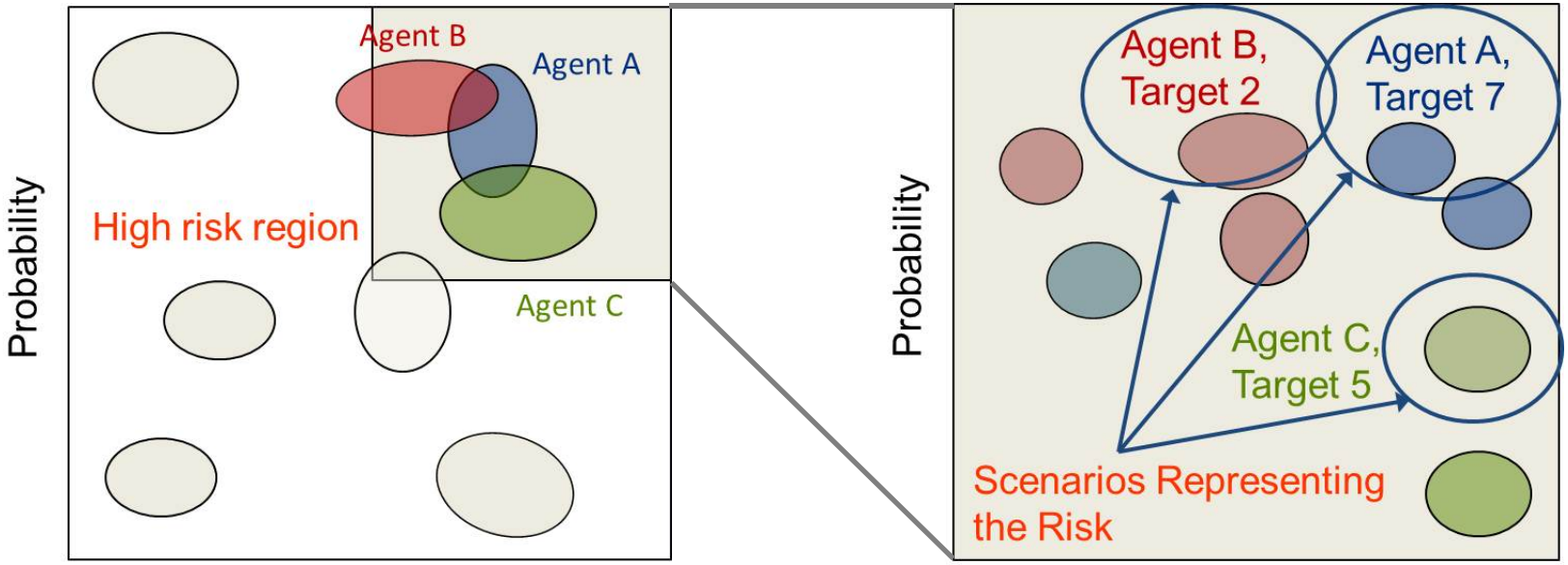
Overall Risk "Ranking" as function of Probability X Consequences

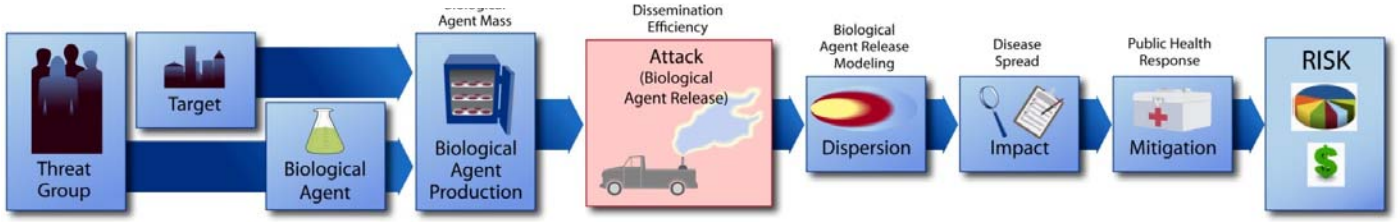


Percent of "Risk" by agent or target

What Contributes to Risk?

- What attack scenarios are of greatest concern?
- Identifying scenarios to inform planning efforts. A smaller set of scenarios may represent a majority of the risk





Stakeholders Currently Using the TRAs

Stakeholder	Project Facilitated by TRAs
HQ	Provide quantitative risk perspective resource allocation and risk mitigation strategies (BTRA/CTRA/ITRA)
FEMA	Informing program plans and risk-based decisions for grant programs (ITRA, BTRA, CTRA) Identified high risk scenarios suitable for chemical strategy development (CTRA)
Operations	Identified high risk scenarios suitable for biological and chemical strategy development (BTRA/CTRA)
CBP	U.S. Global Supply Chain Security Risk Characterization Project (ITRA, RNTRA, CTRA)
CDC	Informing resource decision-making for the SNS (ITRA, BTRA, CTRA)
HHS/ASPR	Countermeasures acquisition planning and preparedness and response program planning (ITRA, BTRA, CTRA, RNTRA)
OHA	Provided city justification for the demonstration project (CTRA)
USDA/FDA	Funded tailored assessments to answer critical food defense issues (BTRA/CTRA)
Sector Partners	Provide quantitative risk perspective to specific sectors (CTRA)
EPA	Inform Standard Analytical Methods development (CTRA)
Fusion Centers	Identified high risk scenarios of concern for planning, preparedness, response and training (CTRA)
DOD	Aligned similar initiatives between DOD and civil defense (BTRA/CTRA)
DOJ	WMD Directorate informed method development and identified high risk scenarios and opportunities for enhanced interdiction (CTRA)
Policy	Provided critical risk information to aid in postal analysis (CTRA) and Strategic National Risk Assessment (ITRA)
NIH	Informed and advanced research related to CounterACT and broad spectrum countermeasures (CTRA)

Conclusions

- DHS uses risk to inform biodefense program planning, resource allocation, operational activities
- DHS supports Homeland Security Partners with information and analysis derived from Risk Assessments to provide a common understanding of the risk and assist in their program planning efforts

Questions?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