Department of Homeland Security
Science & Technology

Presentation to International Conference on Health and Security

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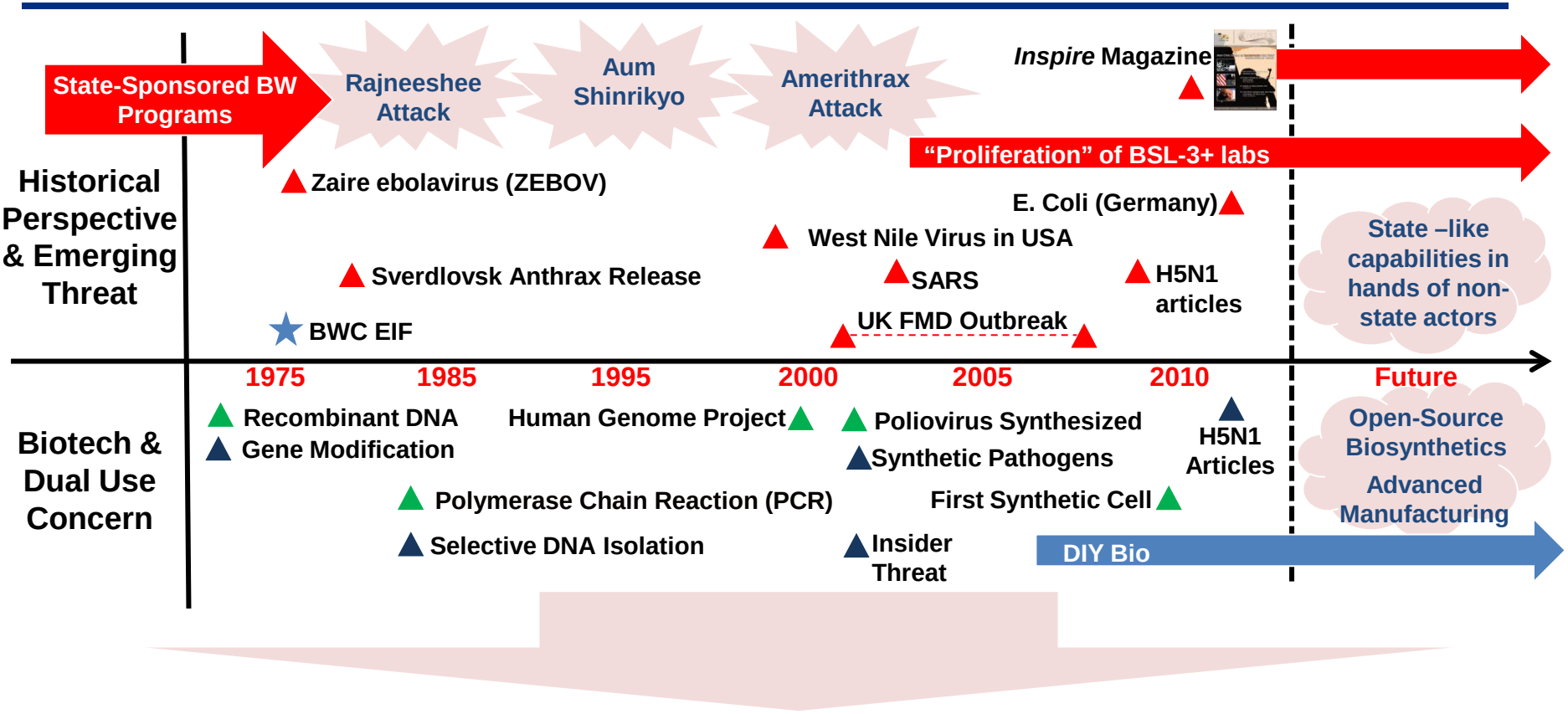
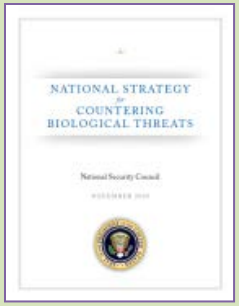
The Nature of the Biological Threat





"The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed one trillion dollars for each such incident."

-- National Strategy for Countering Biological Threats, November 2009

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U.S. Government & DHS Biodefense Programs

Biological Threat Spectrum

Natural Disease Outbreak | Unintended Consequences | Accidents | Negligence | Vandalism, Sabotage | Deliberate Use of BW

Biodefense issues are:
- ❑ International & Interagency
- ❑ Complex & Multidisciplinary
- ❑ Inherently dual use

One Health

Nunn-Lugar Cooperative Engagement (State & Defense)

Biorisk Management: Biosafety, Biosecurity, Bioethics

Australia Group

WHO International Health Regulations (IHR)

UNSCR 1540

Laboratory Response Network (LRN)

BSAT Regulations

Dual Use Research of Concern (DURC)

Bilateral arrangements

BWC

FAO & OIE

Export Controls

Why are Biodefense & Arms Control DHS Concerns?

- **DHS has a major role in the integrated national biodefense efforts including activities in the following areas:**
  - **Biosurveillance**
  - **Threat characterization**
  - **Critical infrastructure protection**
  - **Forensic analysis**
  - **Response & Recovery**

- **U.S. treaty commitments including BWC compliance is a Department level responsibility**
- **The Department's Goals:**
  - **To protect the U.S. Homeland**
  - **To conduct necessary legitimate biodefense while ensuring full and unequivocal adherence to the BWC**
  - **To serve as a member of the National Biodefense Interagency efforts**

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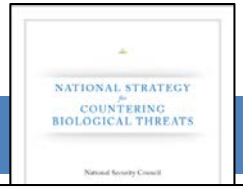
DHS Biodefense: Strategy to Capability

Strategic Guidance

U.S. Federal Law

Homeland Security Act 2002



Countering Biological Threats (2009)

Quadrennial Homeland Security Review (2010)

Operational Directives

- HSPD-9 Defense of U.S. Agriculture & Food (2004)
- HSPD-10 Biodefense for the 21st Century (2004)
- HSPD-18 Medical Counter-Measures Against WMD (2007)
- PPD-2 National Strategy for Countering Biological Threats (2009)
- Biological Select Agent & Toxin Executive Order (2010)
- PPD-8 National Preparedness (2011)

Prevention, Protection, Mitigation, Response, Recovery

Homeland Security Presidential Directive (HSPD)-10 Requirements

- Knowledge Management
- Threat Characterization
- Detection & Surveillance
- Forensics & Attribution
- Response & Recovery

DHS Contributions

- Biological Knowledge Center
- S&T Chem-Bio Division
- Interagency & International Collaboration
- Labs (PIADC/ NBACC)
- First Responders
- Component Collaboration

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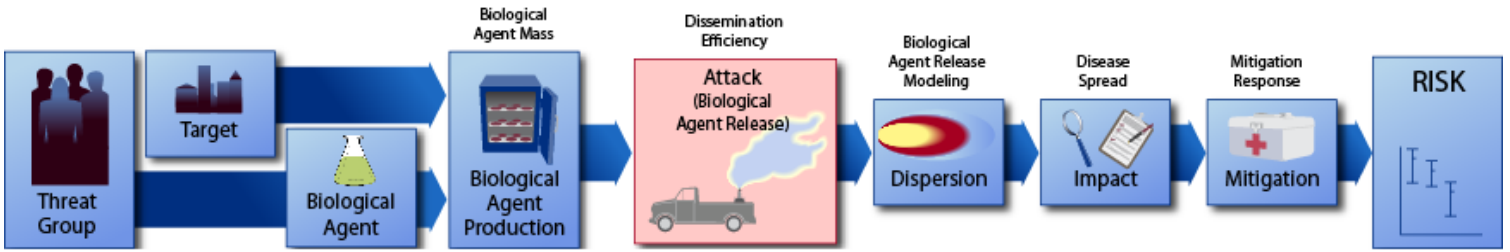
Biodefense: Threat Awareness

Provides in-depth scientific knowledge and expertise regarding specific biological threat agents, the risk of biological attack, and an attack's impact on people and locations, providing service across the Department and interagency

- **Biological Threat Characterization** to address critical knowledge gaps, improve understanding, and reduce uncertainty in risk estimates for policy decisions
  - **Material threat assessments** inform medical and other countermeasure development
  - **Lab studies** to improve understanding of biological agent properties
  - **Bio-Defense Knowledge Center** provides technical reachback and knowledge management
- **Risk Assessments** provide the basis for risk-informed investments for National strategic defense planning, while identifying key knowledge gaps and defining critical vulnerabilities

Bioterror Risk Assessment (BTRA)



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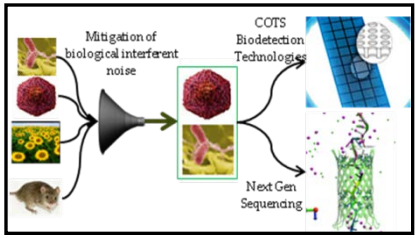
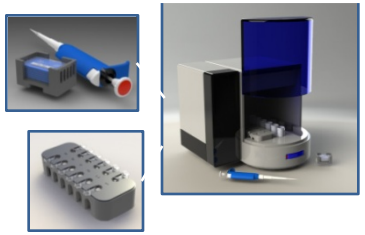
Biodefense: Surveillance & Detection

Facilitates detection process of advanced, emerging, or enhanced biological agents with novel assays, established interagency and industry standards, and new technologies

- **BioAssays** and biological materials repository supports biodetector assay chemistry development and validation efforts for Federal Assays, ensuring accurate detection standards & benchmarks
- **Next Gen Bio Detection** develops a commercial, off-the-shelf platform and a novel sample preparation module for rapid, multiplexed detection of high-priority traditional and emerging biothreat agents
  - **Detect-to-Protect** protection of high value facilities by providing warning and identification of an indoor bio-aerosol threat release and supporting decisions to minimize exposures and extent of contamination
  - **Rapid Biodetection** project is exploring pre-symptomatic diagnostic markers of exposure, along with point of care devices, to enable rapid triage and treatment of individuals
  - **Environmental sampling** system with Biowatch
- **National Biosurveillance Integration Center (NBIC)** coordinates comprehensive national biosurveillance and situational awareness and collaborates with the interagency community on biosurveillance issues

BioAssays	Next Gen BioDetection	Detection Systems
		

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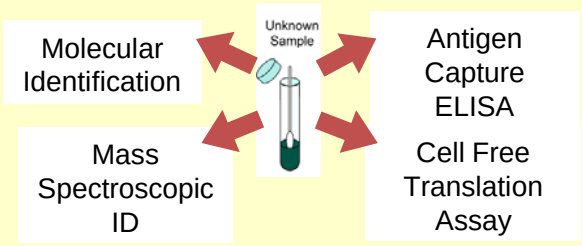
Biodefense: Response & Recovery

Promotes resiliency to bioattacks by identifying technologies and methods to inform the identification of contaminated space, decontamination & support investigations

- **Operational Tools** project works with the interagency to conduct and evaluate field-level facility biological remediation studies of various decontamination technologies
- **Bioforensic Research and Development** project develops new methods to help determine the source and production method of biological agents employed in an incident
  - **National Bioforensics Operations** conducts forensic analysis of evidence in support of FBI efforts to prevent and attribute biocrimes
- **Systems Approaches** for developing guidance in concert with constituency user groups (regional, local) to recover from wide-area biological incidents
  - **Underground Transport Restoration** develops guidance specifically for the recovery of subways, extensible to other transit systems, from bio attacks
  - **Anthrax reaerosolization** project examines the properties of dry powder anthrax to determine guidance, countermeasures and decontamination strategies

Bioforensics

NBFAC



Wide Area Recovery

- **Chem, Bio, Rad**
- **Demo held in Denver**

Operational Tools

Biodefense: DHS S&T Laboratories

❑ National Biodefense Analysis and Countermeasures Center (NBACC)

- National Bioforensics Analysis Center (NBFAC)
  - ➢ Conduct forensics in containment … CDC select agent registered
  - ➢ Laboratory Response Network qualified
- National Biological Threat Characterization Center (NBTCC)
  - ➢ Vulnerability characterization studies
  - ➢ NBTCC Goal is to break the bioterrorist attack pathway

❑ Plum Island Animal Disease Center (PIADC)

- Protect U.S. livestock from the accidental or deliberate introduction of foreign animal diseases (FAD)
- Built in 1954, PIADC is …
  - ➢ Undergoing upgrades to maintain safety and provide added near-term capacity
  - ➢ BSL-3 only … Limited capacity … Serves as a critical resource for FAD
  - ➢ Development of countermeasures … Vaccines, diagnostics, biotherapeutics
- Expect to replace PIADC with National Bio and Agro-Defense Facility (NBAF)

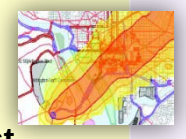
U.S. National Biodefense Collaboration

Fort Detrick Example

Area	Capability	U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID)	National Institute of Allergy and Infectious Diseases Integrated Research Facility (NIAID-IRF)	U.S. Department of Agriculture Agricultural Research Service (USDA-ARS)	Department of Homeland Security National Biodefense Analysis and Countermeasures Center (NBACC)	Health & Human Services Centers for Disease Control & Prevention (CDC)	National Cancer Institute (NCI)
Threat Awareness	Risk/Threat Assessment	■		■	■	■	
	Threat, Vulnerability, Consequences Studies				■		
	Detection				■	■	
	Biosurveillance			■	■	■	
	Genotyping			■	■	■	
	Education/Training	■		■	■		
Prevention & Training	Vaccine Development & Production	■	■				■
	Prophylaxis	■	■				■
	Plant Resistance			■			
	Control Technology					■	
Surveillance & Detection	Surveillance / Detection	■			■	■	
	Diagnostics	■	■	■	■	■	
	Assay Development	■	■	■	■		
	Genotyping		■	■	■		
	Education / Training	■			■		
Response & Recovery	Epidemiologic	■	■			■	
	Risk Assessment	■			■	■	
	Bioforensics				■		■
	Therapeutics	■	■				■
	Clinical	■	■				■
	Decontamination	■			■	■	
	Education / Training	■	■	■	■	■	■

DHS S&T Contributions to Biodefense Mission

Chem-Bio Division
…Save lives & protect Nation's infrastructure against chemical, biological & agricultural threats & disasters.



S&T Labs

Interagency

- ❑ DOE National Labs
- ❑ Defense Threat Reduction Agency (DTRA)
- ❑ Department of Agriculture
- ❑ Others …

International & Academic

International
Federal
State
Local
Tribal
Territorial

Successes (Examples)

- ❑ Foot & Mouth Disease (FMD) Vaccine
- ❑ Rapid point of care diagnostics
- ❑ Biowatch fielding & analysis
- ❑ Medical Countermeasures Development (MCM) support
- ❑ DHS laboratory certification
- ❑ "White Powder" standard
- ❑ Assay development standards
- ❑ Threat characterization studies
- ❑ Bioterror Risk Assessment (BTRA)
- ❑ Bioforensics

Areas of Concern (Examples)

Crisis Management
Agricultural Vaccines
Supply Chain Security
Public Biothreat Education
Forecasting Future Threats
International BSAT Standards
Int'l/Domestic Response Training
Decon of CI/KR (Ag & Bio)
Resilience Communication
Local Response Capability

Integrated Consortium of Laboratory Networks (ICLN)

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Conclusions

- There is an important synergy between national security, public health and law enforcement
- U.S. national cross-cutting biodefense capabilities have been developed to protect from potential man-made or emerging infectious disease events
- National implementation is a foundation for BWC compliance and critical to global biodefense efforts