

U.S. Biodefense & Treaty Compliance

Dr. Daniel M. Gerstein
Deputy Under Secretary for Science & Technology
U.S. Department of Homeland Security

December 8, 2011



**Homeland
Security**

The Nature of the Biological Threat

“... it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013.”

“ ... terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon.”

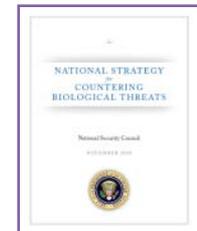
“... the U.S. government needs to move more aggressively to limit the proliferation of biological weapons and reduce the prospect of a bioterror attack.”



COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM

“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



The Biological Threat Spectrum



Fort Detrick's History

- ❑ During World War II era, Camp Detrick played a significant role in the United States' Biological Warfare (BW) research program
- ❑ In 1969, President Nixon halted the U.S. offensive program
 - Since 1969, the research has been purely focused on defensive capabilities including diagnostics, prophylaxis and treatments
 - Many of the former labs were transferred to other agencies such as the Department of Health and Human Services (HHS)
- ❑ The 2001 anthrax letter attacks prompted a significant shift in United States' investment in federal biodefense research
 - Led to the establishment of the National Interagency Biodefense Campus at Ft. Detrick in 2002 consisting of federal laboratories from across the U.S. government

The National Interagency Confederation for Biological Research (NICBR)



An Interagency Campus -- Fort Detrick Capabilities

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						

U.S. Department of Agriculture – Agricultural Research Service (USDA-ARS)

❑ USDA in-house scientific research

❑ Farm-to-table research scope

❑ 900+ projects

❑ 8,000+ employees

❑ 2,100+ scientists

❑ 100+ laboratories



❑ \$1.2 billion annual budget (FY11)

❑ Universities & industry partnerships

❑ International collaboration

❑ Research Program Objectives:

- Basic research on epidemiology, molecular pathways and mechanisms of infection by exotic plant disease pathogens
- Information sharing and reporting on agricultural threats and emerging plant diseases

❑ Food Biosecurity

- Develop detection/screening methods
- Toxicology studies for infectious disease
- Behavior in high risk food matrices
- Development of predictive models
- Development of new processing technologies to remove toxins

*The only large capacity BSL-3(P)
containment greenhouse in the US for
exotic plant pathogen research*



National Institute of Allergy & Infectious Diseases Integrated Research Facility (NIAID-IRF)

- ❑ **Advanced Imaging and Diagnostic Studies to prevent and treat infectious diseases**
- ❑ **Translational research, integrating clinical tools and strategies into high-containment research in order to mitigate the impact of high consequence microbiological threats on human health**
- ❑ **The IRF research portfolio includes:**
 - **Laboratory-based investigations of high consequence infections**
 - **Clinical investigations of high consequence infections**
 - **Research in complex biological systems to bridge laboratory and human experience with high consequence infections**
- ❑ **No classified research**



U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID)

❑ Research on current and emerging biodefense threats resulting in medical solutions to protect the Armed Forces

❑ Program Overview

▪ Pretreatments

- ✓ Vaccines for bacterial, toxin, and viral agents with the current focus on Burkholderia, ricin, and Filoviruses
- ✓ Multi-agent vaccines

▪ Therapeutics for bacterial, toxin, and viral agents

- ✓ Current focus on plague, Burkholderia, botulinum and Filoviruses
- ✓ Special interest in broad spectrum therapeutics
 - Understanding disease causing or host response pathways

▪ Diagnostic technologies

- ✓ Current focus on assay development and standardization
- ✓ Evaluation of next generation diagnostics

▪ Animal Models

- ✓ Safety
- ✓ Evaluate efficacy of vaccines and therapies following infection
 - Vaccine protects from disease
 - Therapeutic enables recovery
 - Best delivery method



- ❑ Built in 1950s and 1960s for 325 personnel
- ❑ Currently houses ~ 850 personnel
- ❑ 18 buildings
 - Supports research & development for all biosafety levels (BSL)
 - 75 rooms in BSL-2,3,4
- ❑ Specialized capabilities
 - Animal care facility
 - Center for Aerobiology
 - Field laboratory training center



National Biodefense Analysis and Countermeasures Center (NBACC)

❑ Characterization of biological threats and bioforensics analysis

❑ National Bioforensics Analysis Center (NBFAC)

- **Conduct bioforensics casework**
 - **Maintain quality management accreditation (ISO 17025)**
 - **Laboratory Response Network qualified**
 - **CDC select agent registered**
 - **Conduct forensics in containment**
- **Expand Bioforensics capability**
 - **Agent-based assays**
 - **Bioforensics repository**
 - **Genomics-based agent identification**



❑ National Biological Threat Characterization Center (NBTCC)

- **Vulnerability characterization studies**
- **Technical feasibility and hazard studies**
- **NBTCC Goal is to break the bioterrorist attack pathway**



Why is Arms Control a DHS Concern?

- ❑ **U.S. treaty commitments compliance is a Department level responsibility**
- ❑ **DHS has a major role in the integrated national biodefense effort including:**
 - **Biosurveillance**
 - **Threat characterization**
 - **Critical infrastructure protection**
 - **Forensic analysis**
- ❑ **Some projects have the potential to raise some concerns**
 - **Our defensive activities sometimes require sensitive research into the offensive aspects of biological agents**
 - **Classified work is equated by some with an offensive program**
- ❑ **Goal:**
 - **To conduct necessary legitimate biodefense while ensuring full and unequivocal adherence to the BWC**



U.S. Law and the BWC

- ❑ **U.S. Law Implements the BWC and Applies to All U.S. Persons – Including DHS Officials and Scientists**

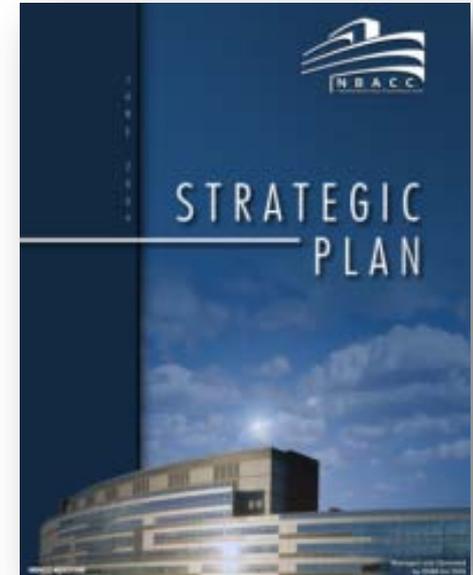
- ❑ **Title 18 U.S. Code Section 175 provides:**
 - (a) **“Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same, shall be fined...or imprisoned for life or any term of years, or both.”**

 - (b) **“Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined... or imprisoned not more than 10 years, or both.”**

 - (c) **“Definition. – For purposes of this section, the term “for use as a weapon” means the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective, bona fide research, or other peaceful purposes”**

DHS BWC Compliance Oversight Process

- ❑ **Integrated but independent oversight for requirements and compliance**
- ❑ **Strategic Plan is reviewed, approved and published**
- ❑ **Projects are reviewed for science and compliance**
 - **External Science & Technology Advisory Committee**
 - **NBACC Institutional Committee review(s)**
 - **DHS and corporate oversight for compliance with:**
 - **All laws and regulations including 18 USC Section 175**
 - **DHS Arms Control Compliance Directive (MD 6300, dated 26 Aug 05)**
 - **DHS compliance review group (CRG)**
 - **CRG is chaired by the Deputy Secretary and includes senior Department representatives for policy, medicine, science, intelligence, and law**
 - **All projects are reviewed before implementation**
 - **Training and outreach program to inform our scientists and officials about our commitments and processes**



The Standard -- BWC Article I Assessment Criteria

Article I contains the provisions most relevant to DHS:

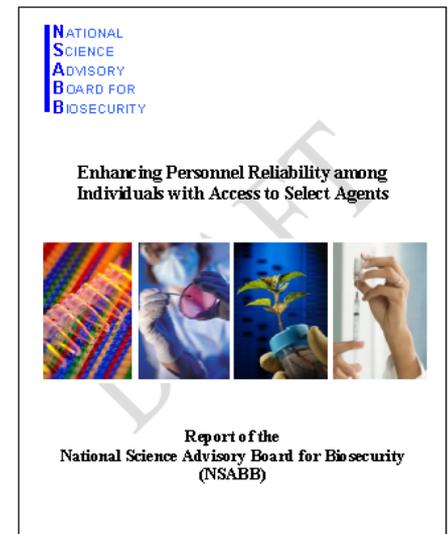
“Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

- (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.”

- Are the *projects* clearly for a prophylactic, protective or other peaceful purposes?
- Are the *types and quantities of biological agents or toxins* used in the projects consistent with and justified for the intended prophylactic, protective or other peaceful purposes?
- Do the projects include any *weapons, equipment, or means of delivery designed to use agents or toxins for hostile purposes or in armed conflict*?

Guidance from National Science Advisory Board for Biosecurity (NSABB) 7

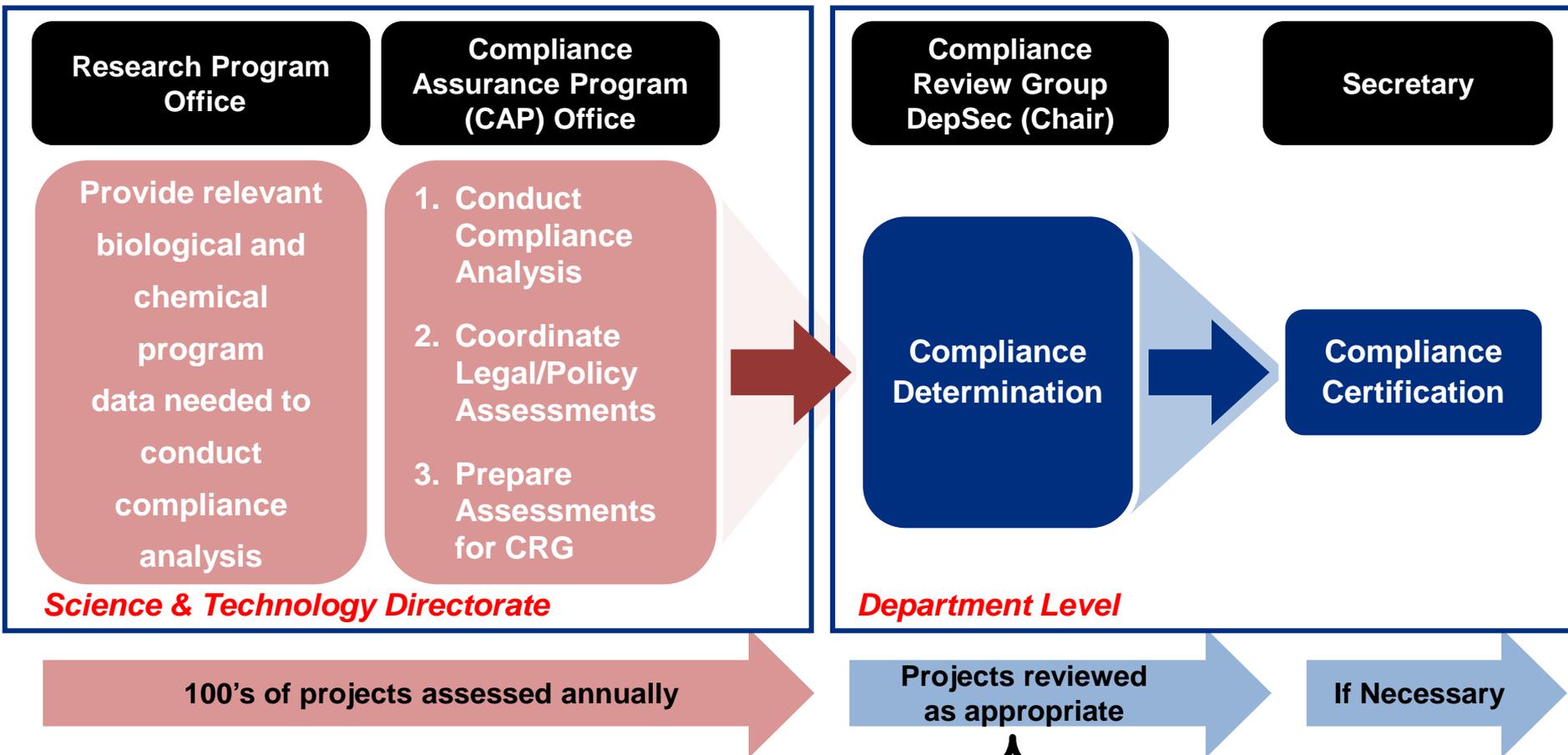
- ❑ **NSABB provided guidance on experimentation in the life sciences**
- ❑ **National Science Advisory Board for Biosecurity (NSABB) 7 “experiments of concern” are those that would:**
 - **Demonstrate how to render a vaccine ineffective**
 - **Confer resistance to therapeutically useful antibiotics or antiviral agents**
 - **Enhance the virulence of a pathogen or render a nonpathogen virulent**
 - **Increase transmissibility of a pathogen**
 - **Alter the host range of a pathogen**
 - **Enable the evasion of diagnostic/detection modalities**
 - **Enable the weaponization of a biological agent or toxin**



Critical Questions for Assessing the Standard – “BWC Checklist”

- Intent of project?**
 - **Will it be involved in any way with development, production, etc., of biological weapons?**
- Use of select agents or toxins?**
 - **Types, quantities and disposition**
- Use of specialized facilities and equipment?**
 - **Biosafety containment laboratories, fermenters, aerosol generators, agent dissemination means**
- Too secretive?**
 - **Desire to have maximum openness except for data on critical U.S. vulnerabilities and information that could be used by our adversaries for the development or use of biological weapons**
- Fostering a bio ‘arms race’?**
 - **We are contributing to US national security in a BWC-compliant manner, and are enabling robust countermeasures to biological threats**
- Enabling proliferation?**
 - **By closely reviewing and controlling those most sensitive, dual-use aspects of the work, we are striving to ensure that we do not enable proliferation**

Compliance Certification Process for DHS Biodefense Programs



Prepared for CRG Review Include **Programmatic**, **Legal** and **Policy** Considerations:

- ❑ **Programmatic:** Gather information from executing organizations in accordance with BWC-focused criteria
- ❑ **Legal:** Law, relevant precedent, treaty interpretation ... Custom/Practice
- ❑ **Policy:** Relevant Presidential decisions, guidelines from White House ... Interagency Input

Characterizing the Biodefense Projects

CAP Office Assessment Results in Project Being Categorized ...

Category	1	2	3
Disposition	Provided in CRG read-ahead book	Briefed to CRG	Program manager, compliance officer briefs to CRG; require CRG member signatures
Level of Concern	Project <u>does not raise any compliance concern</u> in the opinion of the analysts and CAP Office	Project might reasonably raise the <u>perception</u> of a compliance issue, but does <u>not involve NSABB “experiments of concern”</u>	Project might reasonably raise the <u>perception</u> of a compliance issue or <u>involve NSABB “experiments of concern”</u>
Rationale	<ul style="list-style-type: none"> <input type="checkbox"/> Project does not involve NSABB “experiments of concern” <input type="checkbox"/> No dual-use issues identified in project summary 	<ul style="list-style-type: none"> <input type="checkbox"/> Significant dual use issue identified from checklist or summary <input type="checkbox"/> Project will generate data on critical vulnerabilities <input type="checkbox"/> Project involves studies of biological agent production or dissemination 	<ul style="list-style-type: none"> <input type="checkbox"/> Types and quantities of biological agent used raise questions about intent and purpose <input type="checkbox"/> Experimental equipment, procedures or activities raise questions about intent and purpose <input type="checkbox"/> Other ...

Conclusions

- ❑ **National implementation is a foundation for BWC compliance and critical to global biodefense efforts**
- ❑ **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**
- ❑ **DHS arms control compliance assurance mechanisms reflect the letter and spirit of the BWC and U.S. Law**





Homeland Security



Homeland
Security