



# **USG Policy Actions on Biosecurity**

**National Science Advisory Board for Biosecurity  
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# Biosecurity Landscape within EOP

- NSABB Reports:
  - *Synthesis of Select Agents; Framework for Dual Use;*
  - *Education and Training; Enhancing Personnel Reliability;*
- E.O. Working Grp Report: Strengthening the Biosecurity of the United States
- Defense Science Board Report: DoD Biological Safety and Security Program
- Transfederal Task Force Report: Optimizing Biosafety and Biocontainment Oversight
- WMD Commission Report: World at Risk
- NAS Report: Responsible Research with BSAT
- CRS Report: Oversight of High-Containment Biological Labs: Issues for Congress
- GAO Reports: BSL-4 Labs Improved Perimeter Security Despite Ltd Action by CDC
- Draft GAO Report: High-Containment Labs-Coordinated National Oversight is needed
- AAAS Workshop Report: Biological Safety Training as a Component of Personnel Reliability



# Common Themes across many reports:

- Reduce or stratify the Select Agent List;
- Better coordinate inspections across agencies that manage contracts or facilities involving BSAT;
- Clarify standards and guidance across several areas of the Select Agent Regulations;
- Importance of continual “ground level” assessment of personnel after BSAT access is granted;
- Creation of Oversight/coordination body



# Working in response to recommendations

- NSS/OSTP Working Group on Optimizing BSAT Security;
- Working group on Dual Use Research Oversight (DURO)
- synDNA sub-IPC;
- Working group on Biosecurity Outreach and Education;



# NSS/OSTP WG on Optimizing BSAT Security

## POTENTIAL actions/activities\*\*

- Establish Interagency (and possibly External) Board(s) for advising the SAP;
- Stratify and/or Reduce the list of Select Agents and Toxins;
- Promulgate revised Rule(s) and guidance for compliance with SAP;
- Simplify USG policies on BSAT security through centralization/coordination;
- Resolve key issues related to shipping and transport of BSAT

*\*\* Personnel Reliability issues will be covered throughout where appropriate*



# DURO Working Group\*\*

Charge: Analyze the Framework proposed by the NSABB

- Identify gaps, overlaps, and unresolved issues;
- Identify policy options and recommendations for the effective oversight of DUR;
- Develop and promote opportunities for interagency coordination on above;
- Identify opportunities for communication, coordination, and leverage among stakeholders and agencies in specific technical areas related to DUR;

*\*\*Report considered in Biotechnology subcommittee of Committee on Science, National Science and Technology Council (NSTC)*



# DURO Working Group

## Approach:

- Threat briefings, briefings on extant systems of DUR research oversight, etc.)
- Consultation with stakeholders as appropriate (including NSABB)

## Products:

- Outline of Federal Guidelines for Oversight of DUR
- List of additional tools and guidances to be developed



# Synthetic Genomics: USG Policy Actions

- Report issued in previous administration (HSC/OSTP co-chaired PCC process)
- Now part of Interagency Policy Committee (IPC) within NSC, co-chaired by OSTP;
- Series of recommendations continue to be addressed by the sub-IPC;





# Synthetic Genomics: USG Policy Actions

- Harmonize guidance concerning the Select Agent Regulations with respect to synthetically-derived DNA  
*In progress; Update Dr. Tru Twedt*
- Establish a screening infrastructure for use by commercial providers and users of synthetic nucleic acids  
*RFI on Commercial Screening Guidelines is out: Dr. Jessica Tucker*
- Coordinate international outreach on synthetic biology issues  
*State has drafted an outreach strategy and is aiding elevation of topic in international settings*



# Synthetic Genomics: USG Policy Actions

- Amend 18 U.S.C. 175c (variola amendment) and issue a legal interpretation on applicability and scope

*July 2008: DOJ Office of Legal Counsel Opinion Letter “Scope of the Definition of “Variola Virus” Under the Intelligence Reform and Terrorism Prevention Act of 2004*

*Letter disseminated by CDC to Select Agent Officials/institutions and posted : <http://www.selectagents.gov/infoBoard.htm>*

- Update/revise *NIH Guidelines for Research Involving Recombinant DNA Molecules* and *BMBL* to address synthetic biology

*RFI released on Guidelines, Update Dr. Jacqueline Corrigan-Curay*



# Synthetic Genomics: USG Policy Actions

- Reconcile Commerce Control List (CCL) with Select Agent Regulations (Commerce, HHS, USDA)

*Will be addressed upon completion of tasking on SAR guidelines;  
CCL undergoing revision by BIS/DOC via ETRAC;  
New IPC will address;*

- Identify the scientific advances necessary before a predictive oversight system can be postulated, developed, evaluated, and potentially implemented

*National Academies study has launched:*

*May 2009: "Scientific Milestones for the Development of a Gene-*

*Sequence-Based Classification System for Oversight of Select Agents"*

*September 2009: Public meeting*



# Biosecurity Outreach and Education

- Report considered through NSTC, Committee on Science, Subcommittee on Biotechnology
- USG Working group sharing ideas and communication on Biosecurity outreach: *Goal is unified USG message*
  - Development of educational materials; websites, booths for scientific meetings, etc.
- NSABB Working Group on Outreach and Education remains active
  - Will have update today*