



USG Policy Actions on Biosecurity

**National Science Advisory Board for Biosecurity
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**Diane C. DiEuliis, Ph.D.
Office of Science and Technology Policy
Executive Office of the President**



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*