

Synthetic Genomics: Responses by Executive Branch Agencies & Federal Select Agent Program

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Synthetic Genomics

- Wide range of technical tools & research knowledge
- Allow for *in vitro* creation or modification of living organisms
- Although different from older genetic engineering methods (e.g., transformation), on the continuum of modern genetic engineering methods
- Most significant recent developments include advances in the ability to synthesize large DNA molecules with specific sequences
- “Genome engineering,” e.g., design of “new” organisms with novel genomes engineered for specific functions



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Background: Stimulus for Action

- Report, J. Craig Venter Institute
 - *Synthetic Genomics: Options for Governance*
- NSABB Report
 - National Science Advisory Board on Biosecurity
 - WH Policy Coordinating Council
- Requests from Industry
- Requests from Entities



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SYNTHETIC GENOMICS | OPTIONS FOR GOVERNANCE

Overview

Synthetic genomics combines methods for the chemical synthesis of DNA with computational techniques to design it. These methods allow scientists and engineers to construct genetic material that would be impossible or impractical to produce using more conventional biotechnological approaches. For example, using synthetic genomics it is possible to design and assemble chromosomes, genes and gene pathways, and even whole genomes.

Scientists foresee many potential positive applications including new pharmaceuticals, biologically produced ("green") fuels, and the possibility of rapidly generating vaccines against emerging microbial diseases.

However, as with many technologies, there is the potential for misuse and accidents. Finding ways to mitigate possible nefarious uses and to prevent accidents in the laboratories of legitimate users so that positive uses are not undercut is an important concern of scientists, governments, and a large variety of stakeholders.

This report is the result of a 20-month examination of the safety and security concerns posed by this new technology. Including the authors, a core group of 18 individuals with a wide range of expertise undertook three tasks: assess the current state of the technology, identify potential risks and benefits to society, and formulate options for its governance. The report discusses options that would help to enhance biosecurity, foster laboratory safety, and protect the communities and environment outside of laboratories. Three sets of options apply respectively to commercial firms that supply DNA; the oversight or regulation of DNA synthesizers and reagent used in synthesis; and the legitimate users of the technologies, such as university researchers.

Funding

Alfred P. Sloan Foundation

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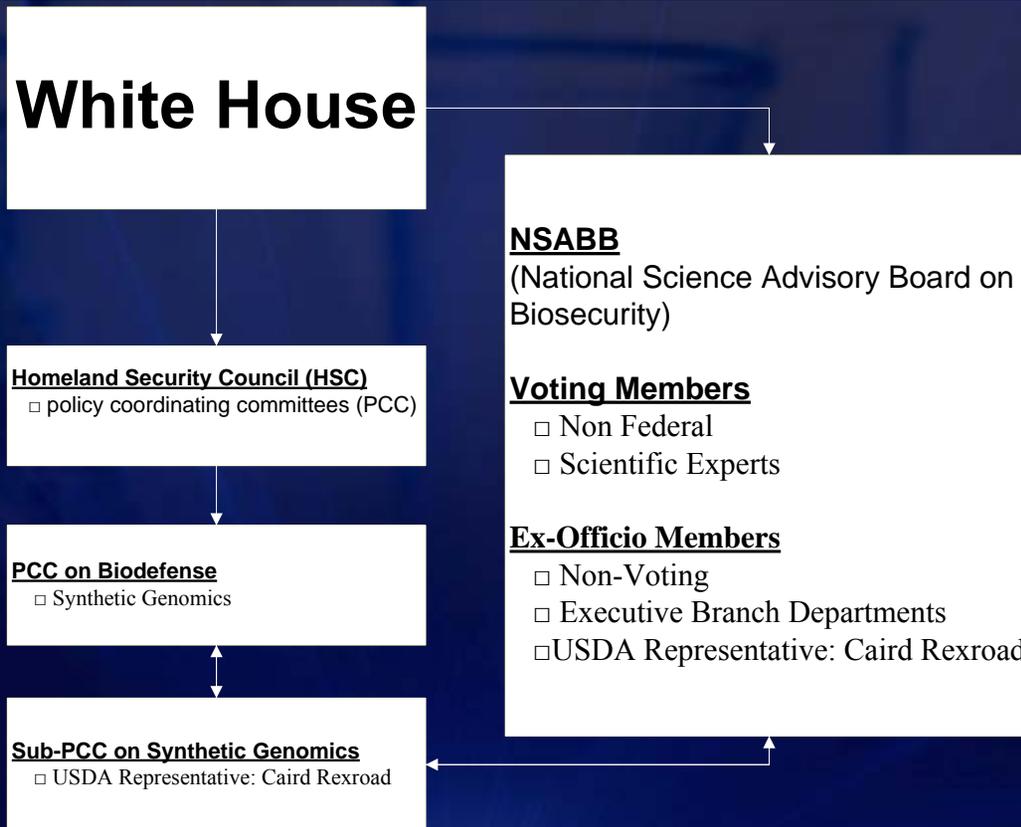
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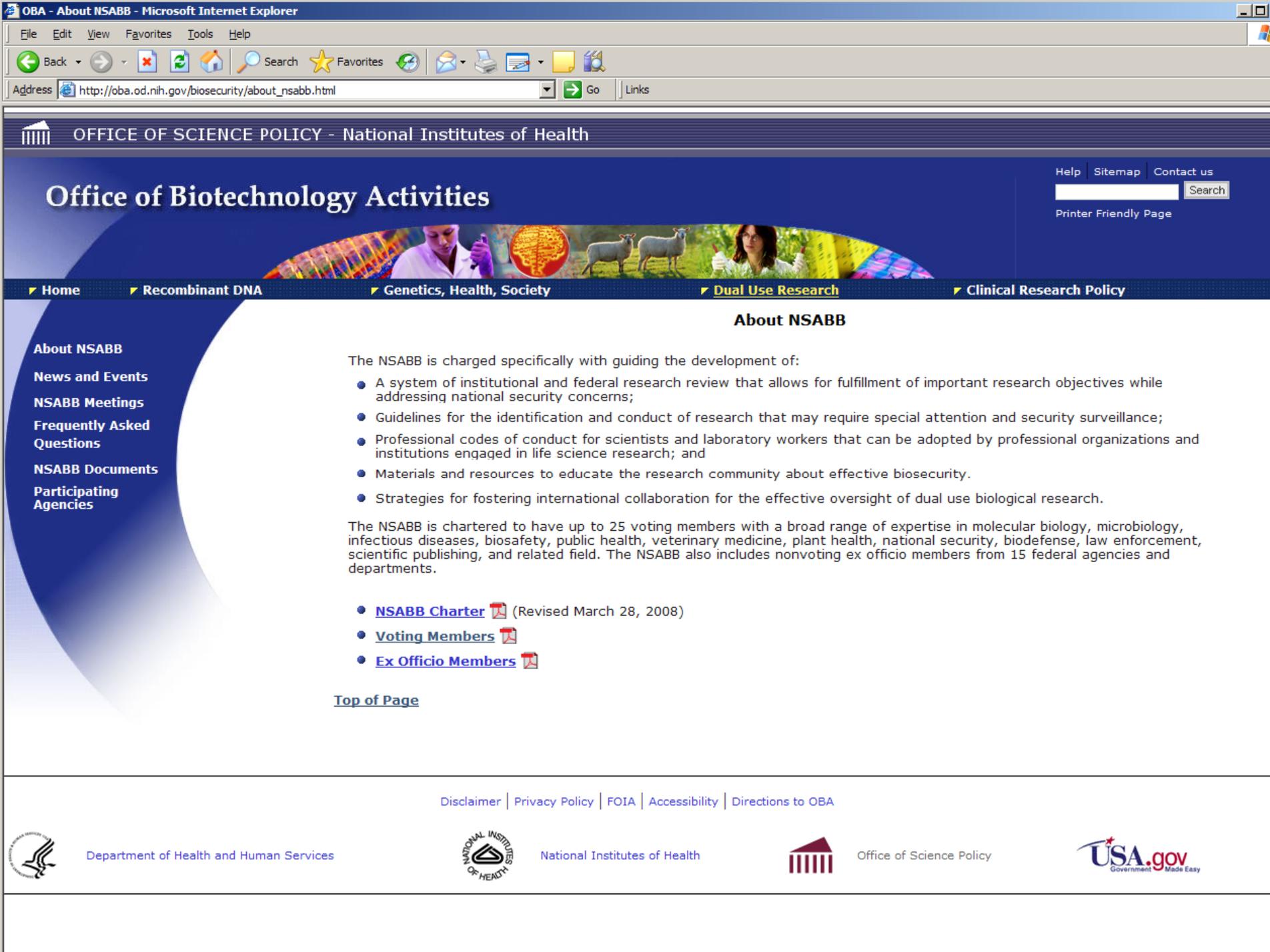


Executive Branch Response to NSABB Report



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Office of Biotechnology Activities

- Home
- Recombinant DNA
- Genetics, Health, Society
- Dual Use Research**
- Clinical Research Policy

About NSABB

- About NSABB**
- News and Events
- NSABB Meetings
- Frequently Asked Questions
- NSABB Documents
- Participating Agencies

The NSABB is charged specifically with guiding the development of:

- A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
- Guidelines for the identification and conduct of research that may require special attention and security surveillance;
- Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research; and
- Materials and resources to educate the research community about effective biosecurity.
- Strategies for fostering international collaboration for the effective oversight of dual use biological research.

The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related field. The NSABB also includes nonvoting ex officio members from 15 federal agencies and departments.

- [NSABB Charter](#)  (Revised March 28, 2008)
- [Voting Members](#) 
- [Ex Officio Members](#) 

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**NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY**

Strategic Plan for Outreach and Education On Dual Use Research Issues



**Report of the
National Science Advisory Board for Biosecurity
(NSABB)**

December 10, 2008



**NATIONAL
SCIENCE
ADVISORY
BOARD FOR
BIOSECURITY**

**ADDRESSING BIOSECURITY CONCERNS
RELATED TO THE SYNTHESIS OF
SELECT AGENTS**

DECEMBER 2006



NSABB Recommendation 1

HHS and USDA should collaboratively develop and disseminate harmonized guidance to investigators and nucleic acid/gene/genome providers concerning the SAR with respect to synthetically-derived DNA.



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NSABB Recommendation 1.1

Increase awareness among investigators and nucleic acid/gene/genome providers about their responsibilities to know what they possess, manufacture and/or transfer in order to comply with the SAR; and



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NSABB Recommendation 1.2

Provide clarification of what genetic elements or genomes are covered by 42 CFR 73.3(c) and 73.4(c) including:

- 1.2.1.** A list of the organisms whose genomes are explicitly covered and where the reference sequence can be found; and
- 1.2.2.** Instructions for whom to contact if an investigator or provider has questions about covered genetic material.



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Current Nucleic Acid Select Agent Regulations (42 CFR 73.3, 7 CFR 331.3, and 9 CFR 121.3)

- Nucleic acids that can produce infectious forms of any of the regulated select agent viruses.
- Recombinant nucleic acids that encode for the functional form(s) of the regulated toxins, if the nucleic acids
 - Can be expressed *in vivo* or *in vitro*; or
 - Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.
- Regulated select agents and toxins that have been genetically modified.



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SA Program Initiatives in Support of NSABB Recommendations

- Developed Guidance Document to assist the synthetic genomics community in understanding current SA regulations
 - List of genomes specifically covered under current SARs
 - ★ Identification of reference sequences
 - Clarification of manufacturer responsibilities under current SARs
 - Communication through national select agent website and participation at scientific meetings



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SA Program Initiatives in Support of NSABB Recommendation #1

- October 6, 2007 1-day SA course at American Biological Safety Association national meetings
- Development of SA informational booth for participation at major scientific meetings
- Dissemination of guidance/informational documents via the national website (www.selectagents.gov)
- Session at December 2008 FSAP Workshop
- Drafter ANPR



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Proposed SA Program Initiatives in Support of NSABB Recommendations

- **Potential Regulatory Initiatives**
 - **Advanced Notice of Proposed Rulemaking (ANPR)**
 - ★ Solicitation of input from stakeholders regarding Federal regulations related to synthetic genomics
 - ★ Target publication of ANPR: 2009



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Executive Branch Action (Part 1 of 2)	Lead
HSC should convene a joint HSC/OSTP* sub-PCC on synthetic DNA to monitor implementation, facilitate coordination, and keep the PCC apprised of progress on policy actions	HSC OSTP
Develop and disseminate harmonized guidance concerning the Select Agent Regulations (SAR) with respect to synthetically-derived DNA	CDC APHIS
Engage stakeholders (industry & academia) to identify, evaluate and support establishment of a screening infrastructure for use by commercial providers and users of synthetic nucleic acids	HHS USDA DHS
Explore the legal options, benefits, and costs associated with the range of implementation options	CDC APHIS
The Department of State should coordinate interagency dialogue, strategy, and international outreach on synthetic biology issues per the general principles outlined in its white paper	Dept. of State

* OSTP= White House Office of Science and Technology Policy



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Executive Branch Action (Part 2 of 2)	Lead
Convene an interagency panel to draft a proposal to amend 18 U.S.C. 175c and issue a legal interpretation to address HHS' request	Dept. of Justice
Update and revise as appropriate the <i>NIH Guidelines for Research Involving Recombinant DNA Molecules and Biosafety in Microbiological and Biomedical Laboratories</i>	HHS
Explore opportunities for reconciliation of Commerce Control List and SAR language in the context of action 1	Dept. of Comm. HHS USDA
Convene a panel to consider the possibility of revision of the SAR to accommodate future advances in synthetic genomics	HHS USDA OSTP
Identify the list of scientific advancements necessary before a predictive oversight system can be postulated, developed, evaluated and potentially implemented	HHS OSTP



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Questions ?



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