MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

28 June 2005

ENGLISH ONLY

Meeting of Experts
Geneva, 13-24 June 2005

Presentations Submitted by the United States[1]

1. Codes of Conduct for the Life Sciences: Past, Present, and Future

What is a "Code of Conduct"?

- Formal statement of values and professional practices of a group of individuals with a common focus, either an occupation, academic field, or social doctrine.
- Defines the expectations and directs the actions of a group.

Examples of Codes of Conduct for the Life Sciences

- The Nuremberg Code
- The Belmont Report
- American Society of Microbiology (ASM) Code of Conduct
- Code of Ethics for the Life Sciences: Somerville and Atlas – (*Science* 2005)

Why a Code of Conduct for Dual Use Research?

- Government cannot oversee all scientists and experiments across the nation
- Offers greatest opportunity for improving security of research at the level of individual scientists
  - Increases understanding of biosecurity
  - Persistent reminder of moral and ethical responsibilities
  - Creates a "culture of responsibility and accountability"
- Sets professional standards that may have legal implications

Analysis of Representative Codes of Conduct

- Provide an overview of trends in the development of codes
- Identify common and distinguishing features among different codes
- Identify factors that may influence a code's utility or success

[1] / **This document is reproduced without editing, as received by the Secretariat.**

Methodology - Identification

Codes were identified based upon:

- Electronic databases maintained by academic Ethics Departments and/or Ethics Societies[2]
- General Internet Searches
- Other Sources:
- By-laws for Professional Groups
- Organizational Internet Websites
- Libraries

Methodology – Selection

- Codes were selected based upon:
- Relevance of sponsoring organization
- Specificity of content
- Potential applicability to biosecurity and/or dual use Research

Methodology – Classification

Codes were classified by:

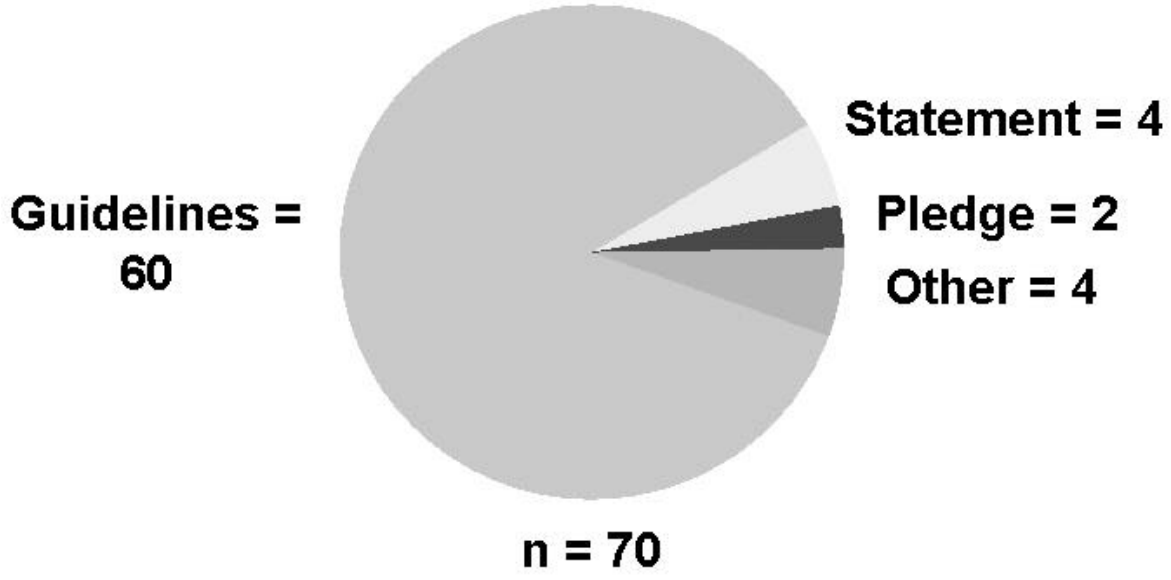
- Group (or Type)
- Sponsor or Initiating Organization
- Year of Initiation/Year of Revision
- Context
- Content (specific vs. unique elements)

Results: Major Groups of Codes

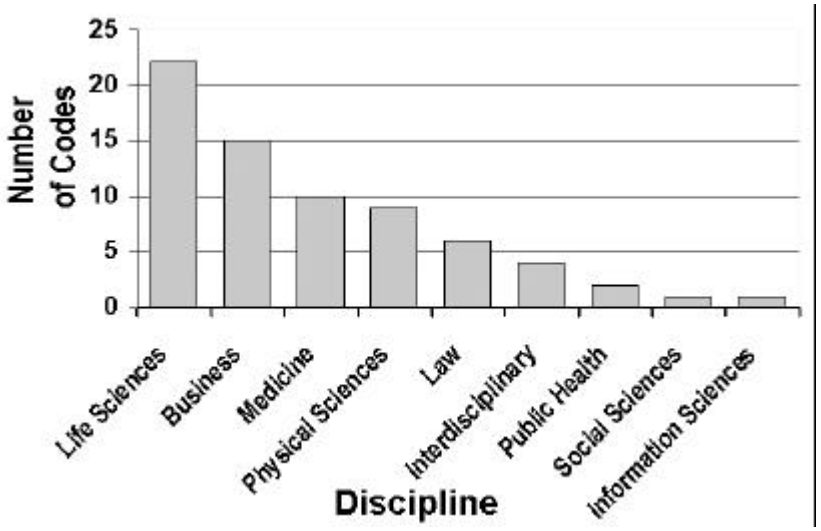
- Guidelines - code, guidelines & principles
- Pledge - oath & pledge
- Statement - appeal, recommendation, manifesto, statement, declaration, resolution
- Others - convention, charter, canon, edict & law

Guidelines Predominate Over Other Types of Codes

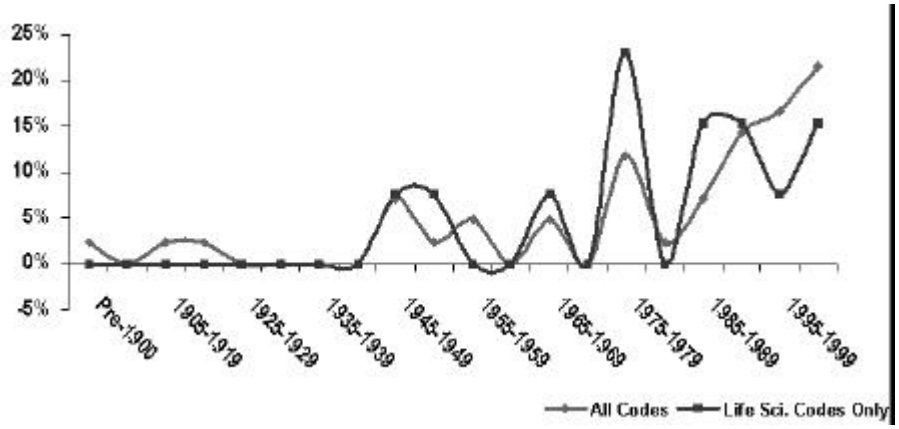
[2] Primary source of codes for this project.



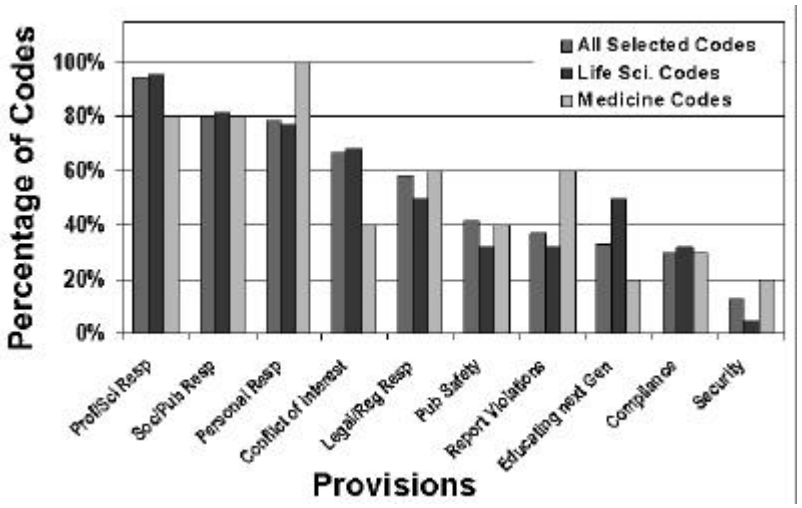
Selected Codes By Discipline



Selected Codes: Promulgation over Time



Selected Codes: Most Frequent Provisions



Findings: Social and Professional Contexts

Most codes addressed relationships between professionals and:

- The public, environment, and/or society
- Colleagues
- Constituencies served

Fewer codes addressed relationships with trainees

Rare But Relevant Provisions

- Security - Preserve national security
- Funding - Fiscal responsibility
- Training - Expectations of mentors
- Confidentiality - Human research subjects

Rare But Relevant Provisions

- Data Integrity - Documentation procedures
- Communication - Communication with media
- Reviews - Protocols and misconduct charges
- Professional Image - Public awareness

Summary

In general, codes of conduct are:

- Found for most professions
- Increasing in number
- Promulgated as guidelines
- Used to train the current and future scientific community in best practices
- Living documents and subject to change

2. The National Science Advisory Board for Biosecurity (NSABB): Enhancing Oversight of Dual Use Research

NSABB: Status and Purpose

- The NSABB is a federal advisory committee
- NSABB will provide recommendations to the U.S. government
- Those recommendations will be directed toward oversight of life sciences research that has been described as "dual use"

The Issue: "Dual Use" Research

Dual use research includes life sciences research:

- with legitimate scientific purpose
- that may be misused to pose a biologic threat to public health and/or national security

Life Sciences: New Considerations

"Dual use" potential of certain life sciences research requires consideration of new processes and procedures designed to minimize the likelihood that biological research will be misused to threaten public health and/or national security.

Life Sciences: Striking a Balance

Goal is to enhance protections for life sciences research while ensuring that any impact to the free flow of scientific inquiry is minimized.

Evolution of the Oversight of rDNA Technology: A Model for Dual Use Research?

1970's: Advent of recombinant DNA (rDNA) technology stimulates concerns among both scientific community and general public regarding:

- Safety
- Environmental impact
- Potential ethical and social implications

History of Federal Oversight of rDNA Technology

- Multiple legislative controls were proposed.
- Scientific community voluntarily adopted a moratorium on rDNA research until an appropriate framework for oversight was established

History of Federal Oversight of rDNA Technology

1974: Oversight Framework established

- Pre-empted pending legislation for regulating all laboratory work with rDNA molecules

- Consisted of three components:
  - Federal
  - Local
  - "culture of accountability" among researchers

Oversight of rDNA Research: Federal Level

- 1974: National Academy of Sciences recommended the National Institutes of Health (NIH) as locus for Federal oversight of rDNA research
- 1975: NIH Recombinant DNA Advisory Committee (RAC) established
- Advise government on principles and procedures for safe and ethical conduct of rDNA research

Oversight of rDNA Research: Local Level

1976: NIH publishes the *NIH Guidelines on Research Involving rDNA Molecules*

- Widely accepted by research community
- Compliance with procedures and principles is a condition for receipt of federal funds for rDNA research
- Voluntary compliance by private sector
- Federally funded research institutions also required to establish local oversight bodies to oversee day-to-day conduct of rDNA research

Oversight of rDNA Research Today

- Oversight system established in mid-1970's still in place today
  - Policies and procedures have evolved with the science
  - Developed in transparent manner with input from scientific community and the public
  - Fosters scientific accountability along with scientific progress
- Offers potential model for oversight of dual use research

NRC Report on Dual Use Research

Report of the National Research Council of the National Academies:
"Biotechnology Research in an Age of Terrorism" ["The Fink Report"] *(October 2003)*

NSABB Charge

- Advise United States departments and agencies that conduct or support life sciences research
- Advise/recommend strategies for oversight of federally supported dual-use research
- Not intended to review specific experiments, except as specified in its charter.
- NSABB Charge

Recommend:

- Criteria for identifying dual use research
- Guidelines for oversight of dual use research
- Strategies for oversight of new classes of experiments and technologies

Advise on:

- Program for biosecurity education and training for scientists and laboratory workers in life sciences
- A code of conduct for scientists and laboratory workers
- National guidelines on communication and dissemination of dual use research methodologies and results
- Strategies for coordinated international policies regarding dual use research

Forming a Federal Advisory Committee: Critical Considerations

Design committee framework (i.e., purpose, structure, operations) to adequately address issues of concern

- Define committee scope and authority
  - e.g. NSABB provides advice to a broad range of US government agencies and departments (18)
- Ensure that activities of committee are transparent and provide opportunity for public awareness and input

Forming a Federal Advisory Committee: Critical Considerations

- Membership selection must take into account:
  - Appropriate expertise
  - Broad geographic representation
  - Population diversity
- Candidates must be screened for conflict of interest
- In addition, NSABB candidates must undergo security clearance

NSABB - Structure and Operations

- 25 voting members appointed by Secretary, HHS, after consultation with other Federal Agencies
- Meets quarterly and as needed
- Meetings open to public, unless otherwise determined by the Secretary, HHS
- Will be managed and administered by Office of Biotechnology Activities, NIH

Examples of NSABB - Member Expertise

- Microbiology
- Clinical ID/diagnostics

- Lab biosafety/security
- Public health/epidemiology
- Health physics
- Pharmaceutical production
- Veterinary medicine
- Plant health
- Molecular biology/genomics
- Bioethics
- National security
- Biodefense
- Institutional Biosafety Committees
- Export controls
- Law, law enforcement
- Scientific publishing

NSABB - Department and Agency: *Ex Officio Members*

- Exec. Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Defense
- Environmental Protection Agency
- U.S. Department of Agriculture
- Department of Interior
- National Science Foundation
- Department of Justice
- Department of State
- Department of Commerce
- National Aeronautics and Space Administration

First NSABB Meeting June 30 and July 1, 2005

- Criteria for identifying dual use research and research results
- Code of Conduct for life sciences research
- Communication of dual use research results
- Strategies for coordination of international policies regarding dual use research
- Synthesis of genomic sequences

Conclusions

- Concerns exist about the intentional misuse of research
- Risks to public health and security from misuse could be immense
- Recombinant DNA Advisory Committee provides a model for the NSABB, as noted by the National Research Council

- NSABB will provide cogent recommendations to US government for oversight of dual use research
- NSABB will carry out its work in a public and open process

http://www.biosecurityboard.gov

3. Professional Responsibility in Agricultural Research

Agricultural Research Service (ARS)

Mission: Conduct research to meet the food and fiber needs of the nation; to sustain a competitive agricultural economy; and to enhance the natural resource base and the environment.

- Intramural research arm of the USDA
- Conducts research to support regulatory and "action" agencies (FSIS, APHIS, FNS, NRCS)
- Extensive collaborations with academia and industry
- Over 100 locations throughout the country

Ethical Issues Related to Agricultural Research

- Scope of agricultural research is of great economic, health and environmental impact:
  - Food safety and human nutrition
  - Plant production and protection
  - Animal health and animal protection
- Nature of the research has high potential for misuse of research findings
  - High consequence events

ARS Code of Ethics

- I dedicate myself to the pursuit and promotion of beneficial scientific investigation, consistent with the mission of the ARS.
- I will never hinder the beneficial research of others.
- I will conduct, discuss, manage, judge, and report science honestly thoroughly, and without conflict of interest.
- I will encourage constructive critique of my personal science and that of my colleagues, in a manner that fosters harmony and quality amid scientific debate.
- I recognize past and present contributors to my science and will not accept unwarranted credit for accomplishments of others.
- I will maintain and improve my professional skills and be a mentor to others.
- I will ensure safety and humane treatment of human and animal subjects and will prevent abuse of resources entrusted to me.

Issues Related to the ARS Code of Ethics

- Developed prior to concerns over homeland security (pre - 9/11)
- Aimed at personal behavior
- Does not adequately address societal issues such as environment, "dual use" of information, etc.

Responsible Conduct by Scientists

- Conduct research in light of existing policies:
- Protection of human subjects, animal care and use, radioactive material use, etc.
- Protection of the environment, workers, and the general population
- Protection of intellectual property
- Concerns over "dual use" of information

Challenges to Responsible Conduct

- ARS is strictly a research agency – it does not conduct classified research
- Freedom to publish is a primary concern but we must be aware of potential misuse of published information
  - Scientist recognition and promotion is dependent on publication
- Education of scientists on the dual use of information
  - Science regarded as an "open enterprise"
- Safeguards, physical and intellectual, must be developed and put in place
- Cooperation with universities, industry & international collaborators is a particular challenge

Responsible Use of Research Facilities

- Agricultural threats require containment facilities
  - Responsible conduct of research
  - Potential for environmental damage
  - Responsibilities of scientists to follow procedures
- Potential hazards of zoonotic diseases
  - Health of workers, coworkers and public
- Open nature of agriculture and food production and distribution

ARS Priority Setting

Concerns Over Research Priorities

- Are the needs of stakeholders and customers the same as those of ARS?
- Are they in the public interest?

- How can and should ARS protect information developed in collaboration with others (such as cooperators)?
- How can ARS protect information provided to others?

4. Implementation of the Biological Weapons Convention

DoD Treaty Management

DoD Directive 2060.1

- Subject: Implementation of, and Compliance with, Arms Control Agreements
- "It is DoD Policy that all DoD activities shall be fully compliant with arms control agreements of the U.S. Government."

Regulatory Framework

- The U.S. DoD has long-standing internal methodologies to ensure safety and security of dangerous items and substances
  - Procedures cover chemical, biological, medical, radiological, high explosive, and other items
  - Codified in extensive procedures to ensure protection of personnel and the environment
- DoD complies with all requirements of U.S. national law and regulations
  - This includes compliance with arms control obligations
  - DoD Directive 2060.1 Implementation of, and compliance with, Arms Control Agreements

Acquisition Program Management

- A key aspect of U.S. DoD procedures and precautions is careful review and management of research, development, and acquisition programs
  - DoD requires the conduct of legal reviews of all acquisition programs, including compliance with arms control obligations
- Two reviews are required for developmental systems
  - Before initiation of engineering development
  - Before awarding the initial production contract
- Non-developmental items are reviewed prior to their acquisition
  - DoD Directive 5000.1, Defense Acquisition System

Biodefense Program Management

- U.S. DoD has recently established a new technical senior biodefense group to integrate efforts at the Department level
- Seeking better cooperation and coordination of efforts among government, industry, and academia
  - Partner with other government agencies & industry
  - Parallel processing of technologies and candidates
  - Downselect to candidate development
  - Fund most appropriate and promising biodefense technology solutions

Research Facility Safeguards

U.S. DoD implements U.S. national safeguards for biological select agents and toxins (BSAT)

- U.S. national standards from CDC/USDA establish the minimum requirements
- DoD adds additional personnel and physical security, reliability, and safety requirements
- DoD specifies a baseline vulnerability assessment for all DoD labs
- DoD requires registration and reporting of labs and programs
    - DoD Directive 5210.88, Safeguarding Biological Select Agents and Toxins

Improving Facility Safeguards

New U.S. DoD regulations are being developed

- Many improvements go beyond the CDC/USDA Select Agent requirements
    - Additional layer of background investigations
    - drug screening
    - medical surveillance
- Interviews and surveillance by supervisors, workers, and self reporting to enhance/ensure reliability and highest level of personnel conduct
- Security enhancements to labs to include
    - intrusion detection systems
    - facility/lab/freezer locks
    - video surveillance of BSAT labs
- Annual drug screening, medical surveillance, and periodic reinvestigations
- Independent compliance inspections of BSAT labs

Biosafety and Biosecurity Rules

Federal guidance requires institutions receiving grants to establish biosafety committees

- Biosafety committees review research proposals and protocols for ethical behavior, especially for projects involving recombinant DNA projects
- These review committees are mandated and monitored by the DoD and the CDC

A DoD Code of Conduct?

- DoD is committed to the legal, ethical, and appropriate operation of its biological defense research and development activities
- DoD believes that it has important elements of a code already in place through regulations
- DoD will continue to examine ways to improve its biosafety and biosecurity programs – possibly with improvement to training modules related to ethical practices in biological research and development
- DoD takes its commitment to the BWC seriously and constantly examines its programs and activities to ensure optimal compliance

5. Developing an Acceptable Code: A Code of Ethics

Overview

- Introduction: Seattle Workshop
- Baseline: Assumptions Underpinning a Code
- Moving Forward: Key Questions for Discussion
- Next Steps

Seattle Workshop

- Held in Seattle, Washington, March 17th-18th , 2005
- Expanded focus from biology to "life sciences"
- Included representatives from national laboratories, federal agencies, and academia
- Solicited feedback regarding code development and implementation
- Workshop Goals:
  - Engender discussion on potential content, costs, and benefits of codes of conduct for use in the U.S.
  - Understand the concerns of those working in the life sciences regarding the ramifications of a code
  - Begin a discussion of a process leading to steps for the establishment of any code for life sciences in the U.S.

Overarching Lesson

Important to introduce scientists to a code of conduct by describing the potential scope of a code and presenting a well-formulated rationale regarding the benefits scientists might receive from a code

Scope of a Code

- Assumptions underlying an acceptable code
- Code Content: Elements of an acceptable code
- Institutional Infrastructure: Implement and maintain a code
- Stakeholders: Individual and organizational involvement

Features of a Potentially Acceptable Code

- Code should not impede scientific discovery while addressing national security needs
- Code should be voluntary at the national level; no mandatory enforcement
- Code should be rigorous, yet it must be flexible
- Code should be assessed periodically and revised as necessary
- Implementation of code should be via existing professional scientific societies as opposed to government
- Code should use existing infrastructure to implement code when feasible

Seattle Workshop Suggestions for Code Content

- Ensure science benefits mankind/does no harm
- Ensure right to advance scientific knowledge
- Obligate individuals to identify/call out unethical behavior
- Obligate individuals to know the quantity and content of material and knowledge they possess and who should be granted access
- Consider dual use implications before dissemination of information, knowledge, materials and technology
- Ensure peer review for safety, security and ethical implications
- Obligate individuals to abide by applicable U.S. laws and regulations, and international treaty requirements
- Enable individual's right to refuse participation in unethical science
- Communicate the code and code precepts
- Ensure code reassessment and reevaluation

Institutional Infrastructure for Code Implementation

- Identify existing structures which could be used to develop and maintain a code
- Develop leadership and advocacy for code infrastructure
- Establish review boards for proposals and publications
- Create avenues for individuals or organizations to report concerns
- Develop programs for training, education and outreach
- Ensure organizational and individual accountability
- Ensure accountability for the principles of the code – without undermining support for the code

Stakeholders

- Wide range of stakeholders with whom to identify and communicate
- Need stakeholder buy-in early in the code development process
- Need further discussion regarding impact of code on stakeholders

Key Questions

- Burdensome Procedures and Regulations
- Feasibility and Effectiveness of a Code
- Knowledge Management
- Authority for deciding research direction
- Universality of application
- Participation level of scientists

Potential Benefits

- Increased Public Confidence through better Accountability
- Trigger to Streamline Policies and Procedures

- Better Awareness of the Dual-use Applications of Science
- Improved Public Communications

Conclusions

- Several different kinds of codes – codes of practice, codes of conduct, codes of ethics
- Participants agreed that a code should *not* be regulatory in nature – a code *should* raise the individual's awareness of ethical issues
- The sense of the discussion was that a code of ethics, as opposed to a code of conduct, is needed
- Key benefit of a code would be to create a value-driven social norm
- Social norm would not strictly enforce or regulate scientific research; it would be similar to the physician's Hippocratic Oath
- Signing the code would be voluntary; living according to its principles would not be because the code would create a set of social and scientific standards

Next Steps in Developing a Code

- Key components of code development process include:
- Defining scope and goals of code
- Stakeholder communication and education
- Public communication and education
- Developing institutions and infrastructure to support and maintain code
- A systematic process for developing a code may not be well-accepted
- Variety of opinions among workshop participants – need to test conclusions with other stakeholders
- Process of code development and implementation may differ

6. Scientist Reaction to a Code: DOE National Laboratories Example

Overview

- Initial Assumptions
- Context for Scientific Oversight
- Survey Process
- Findings of Discussions with Scientists
- Recommendations

Initial Assumptions

- Public: A code would be an effective vehicle for assuaging public concerns regarding the pernicious use of scientific discoveries
- Scientific Community: A code would raise awareness among scientists of the BWC, its obligations, and the dual-use nature of the life sciences
- International: A code would extend responsibility for helping implement the provisions of BWC to the level of individual scientists

Context for Scientific Oversight

International Organizations/ Agreements

Biological Weapons Convention (BWC)
National Confidence Building Measures (CBMs)

National Organizations

Dept. Health & Human Services
NSABB *(Code of Conduct)*, rDNA Advisory Committee (RAC)

Professional and Industrial Associations

Biotech and Pharma Associations — *Code of Conduct*
Editorial Boards for Journals — *Security Review Guidelines*

Research and Development Organizations

Universities	Private Industry	Government Laboratories
Institutional BioSafety Committees, Codes	*Institutional BioSafety Committees, Codes*	*Institutional BioSafety Committees, Codes*

Individual Professionals

Survey Sample

- Interviews and seminars across multiple levels, including managers and bench-scientists
- Spoke with scientists representing a variety of disciplines within the life sciences, including staff working in/on:
    - Fundamental sciences (environmental, molecular, chemical)
    - National security (biodefense)
    - Internal Review Boards / Internal Review Committees (IRBs / IRCs)

Overview of Findings

- Weak understanding of the implications of dual-use capabilities posed by research in the life sciences
- Lack of clarity as to how a code would mitigate bioweapons proliferation and reduce the threat posed by bioterrorism
- Questions regarding the impact on ability to publish and freedom to pursue research
- Code application to only life sciences seemed discriminatory
- Resistance to more government regulation of research

BWC and Dual-Use Issues

- Scientists have minimal control over long-term use of research
- Need efficient mechanism for judging what is dual-use
- Are there any areas of research in the life sciences that are not seen as being inherently dual-use?
- Dual-use education of those pursuing careers in the life sciences must begin at the university level and be continually reinforced

Costs and Benefits of a Code

- Do the costs to scientists of introducing a code balance the benefits to society?
- Is the potential loss to society of scientific advancement balanced by a quantifiable reduction in the BW threat?
- Scientists need to be convinced that the impact of a code of ethics could deter would-be proliferators
- A consideration of costs and benefits is especially relevant if considering restricting publications

Application and Enforcement

- A code cannot be applied uniformly across all life science disciplines and across all countries
- Scientists preferred implementation through professional organizations or societies rather than government
- Does the burden of determining what research has weapons applicability fall on individuals or on organizations?
- Scientist concerns that a code would create a “domino effect” with increasingly stringent enforcement mechanisms

- What is an appropriate mechanism for protecting those who call out unethical behavior?
- How to ensure that a code does not result in overzealous public scrutiny of science?

Recommendations

- Involve scientists and representative organizations early on and throughout the process
- Get the assistance and support of organizations to whom scientists look for leadership (e.g., American Society for Microbiology)
- Recommendations (cont.)
- Provide clear evidence that there is a need/problem that a code of ethics could help solve
- Demonstrate the benefits derived from formulating and adopting a code
- Frame the code around responsibility in the biological sciences
- Avoid alienating scientists by implying they need to be convinced to conduct responsible research
- Recommendations (cont.)
- Need to provide sufficient detail about scope, approach, and implementation of a code to enable realistic estimates of costs
- Broad-based outreach must accompany the process to develop a code

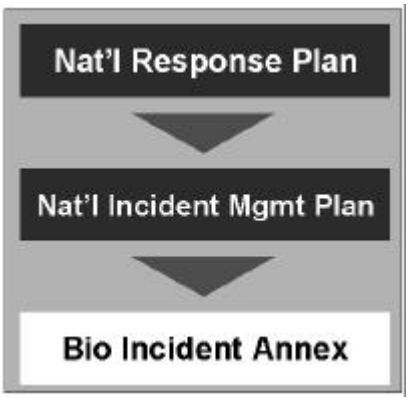
Conclusion

- In general, scientists agreed that there could be awareness raising and educational benefits to developing a code of ethics
- Including other stakeholders, such as industry, NGOs, and the public, is necessary to enable decision on whether and how to move forward with a code

Professional responsibility at the U.S. Department of Homeland Security

- DHS is committed to scientific professional responsibility. At present, a combination of regulatory and procedural oversight ensures ethical conduct.
- DHS will participate in the work of the NSABB, including providing recommendations on a code of conduct for scientists.

DHS has a major role in the integrated national biodefense



- DOS: international aspects
- HHS: medical countermeasures, response, and mass casualty care; anticipate future threats
- EPA: decontamination
- DHS: assessments; critical infrastructure protection; attack warning;forensic analysis; response planning; risk communications
- DOD: Medical countermeasures, detection & diagnostic technology, support in mass casualty events

DHS Biological Countermeasures Program Areas

- Threat Awareness and Characterization – engage facilities and expertise in public and private sectors to support systematic biothreat risk assessments. This includes development of standardized protocols and standards for threat characterization.
- Forensics – establish a lead national facility for technical analysis of forensic samples from biological events.
- Systems Studies and Decision Support Tools – conduct biodefense analysis and strategy planning to guide national biosurveillance monitoring.
- Surveillance and Detection Operations – utilize operational fixed and field deployable biodetection systems (Biowatch Program).
- Surveillance and Detection R&D– develop new technologies for biodetection. Integrates multiple data streams to detect and to respond to an event.
- Response and Restoration – develop pre-approved protocols and decontamination capabilities for facilities.
- Agriculture – provides facilities and programs to develop animal vaccines and next generation diagnostics for foreign animal diseases.

Biodefense and DHS

Under U.S. federal law and the National Biodefense Policy, the Department of Homeland Security (DHS) has national responsibilities for:

- Biological Threat Awareness and Characterization
- Bioforensics

National Biodefense Analysis and Countermeasures Center (NBACC)

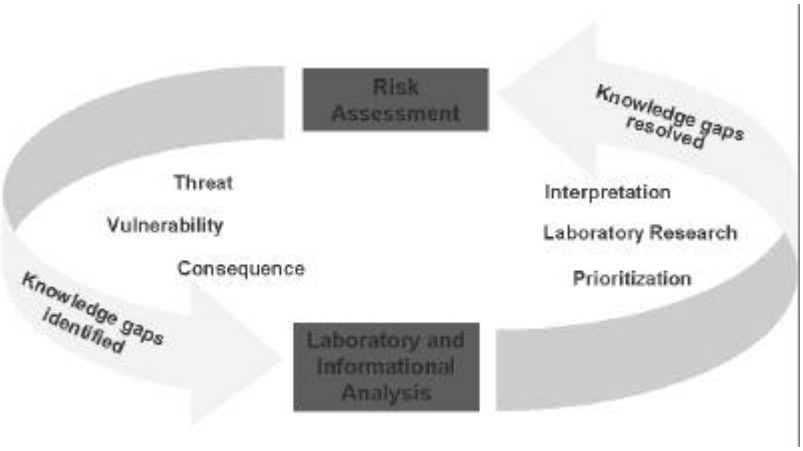
Provide the U.S. with the scientific basis for awareness of biological threats and attribution of their use against the American public

- Biological Threat Characterization Center
- National Bioforensic Analysis Center

National Bioforensic Analysis Center will… deter, prevent, or stop potential criminal, terrorist or state sponsored biological events and provide data for attribution analyses and interdiction.

Biothreat Characterization Center will… characterize biothreats, anticipate future threats and conduct comprehensive risk assessments … to anticipate, prevent, respond and recover from an attack through the establishment of an integrated science-based program and infrastructure.

Closing Critical Risk Knowledge Gaps



DHS Biological Countermeasures Programs Must Meet Domestic Requirements

BWC Implementing Legislation

- U.S. Public Law 101-298 implements the BWC and applies to all U.S. research
  - Includes criminal sanctions for anyone "who knowingly develops, produces, stockpiles, transfers, acquires, retains or possesses any biological agent, toxin, or delivery system for use as a weapon …"
- The Patriot Act of 2001 expands BWC prohibitions relating to bioterrorist activities in the U.S.
- Other Laws and Regulations
  - Animal Welfare Act and its associated Regulations
  - CDC Regulations governing the registration of facilities and personnel for storage, use and transport of biological select agents and toxins
  - NIH Guidelines on research involving Recombinant DNA
  - CDC/NIH Guidelines on Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - Environmental statutes and regulations

DHS Compliance Review

Technical Review

- NBACC protocols undergo scientific peer review to assess their scientific merit
- Standing Committee of the National Academy of Sciences assisting DHS in the peer review process.

BWC Compliance

- All research potentially within the scope of the BWC will undergo rigorous BWC legal and policy review - - in addition to the regulatory and technical reviews noted above
- DHS is formalizing a compliance review structure to review all research potentially within the scope of the BWC
- The compliance review processes will be separate and distinct from the program offices sponsoring the research.
- The DHS compliance program is similar to that of other agencies.
- DHS consults with other agencies on BWC implementation issues.
- DHS participates in an interagency review process for compliance issues led by the National Security Council and the Homeland Security Council

DHS BWC Compliance Review Process

Codes of Conduct

DHS takes its BWC obligations seriously and will ensure that its programs fully comply with the BWC and related statutes.

- Programs are vetted in a rigorous Department-level compliance review and are consistent with U.S. laws and policies pertaining to biological research.

U.S. laws, regulations, guidelines, and DHS agency procedures contain ethical guidelines for our day-to-day activities.

- DHS is developing a training module for researchers that focuses on ethical imperatives.

DHS continually examines ways to improve its biological research, safety, and security training, and welcomes the opportunity to participate in discussions on codes of conduct.

Acronyms

CDC	Centers for Disease Control and Prevention
DHS	US Department of Homeland Security
DOD	US Department of Defense
DOS	US Department of State
EPA	US Environmental Protection Agency
NIH	National Institutes of Health
HHS	US Department of Health and Human Service
NBACC	National Biodefense Analysis and Countermeasures Center

The National Biodefense Policy describes an integrated end-to-end biodefense strategy