Ensuring Compliance With the Biological Weapons Convention

Meeting Report

July 2009

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MEETING ON BWC COMPLIANCE REVIEW PROCESSES

Sponsored by

Center for Arms Control and Non-Proliferation

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Introduction

The 1972 Biological Weapons Convention (BWC) was the first international treaty to completely prohibit the development, production and stockpiling of an entire class of weapons. By signing the Convention, nations state their determination "to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons," and their conviction that "such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk." Accordingly, signatories commit to honoring the prohibitions of the Convention.

The central prohibitions of the treaty are stated in Article I:

> 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.

The commitment to abide by these prohibitions has not always been honored by every State Party to the Convention, and concerns about the activities of some nations persist. Meanwhile, the failure to conclude a verification protocol for the Convention, coupled with the significant growth of biodefense research and development programs over the last decade in response to concerns about bioterrorism, has placed new pressure on the prohibitions contained in Article I. Some have argued that (almost) any activity conducted with defensive intent will be compliant with the BWC. Others argue that the issue of BWC compliance is more complex and demanding, and that framing compliance with the Convention in terms of "defensive intent" may undermine the Convention and increase, rather than decrease, the risk of biological weapons development and proliferation.

There is growing recognition that States Parties engaged in biodefense research and development activities must take active steps to ensure their own compliance with the Convention and to effectively reassure others of their compliance. The Center for Arms Control and Non-Proliferation, together with the Center for International and Security Studies at the University of Maryland, the AAAS Center for Science, Technology and Security Policy, and the Center for the Study of WMD at the National Defense University (Washington, DC), organized a meeting on the processes used by several States Parties to the BWC to assess and ensure their own compliance with the Convention.

The purpose of the meeting, held in Washington, DC on 25 February 2008, was to facilitate information sharing and discussion among a small group of governmental and non-governmental experts about the processes used by various governments and government agencies to ensure their compliance with the BWC. Its goal was to increase participants' understanding of these processes and their underlying rationales, similarities, and differences, as well as to discuss issues surrounding the sharing of compliance-related information. Meeting

participants presented, examined, and discussed compliance mechanisms and processes of Australia, Canada, Germany, the United Kingdom, and the United States. The co-sponsors hope that the results of this meeting, presented in this report, will encourage similar discussions among a widening range of nations.

An overview of the compliance mechanisms and processes presented at the meeting is provided in Table 1 below. Table 1 also provides information on the size and other characteristics of the corresponding biodefense research and development programs. Part I of this report provides detailed summaries of the compliance mechanisms and processes, while Part II summarizes the subsequent discussion.

TABLE 1 Characteristics of Biodefense Research and Development Programs and Their Mechanisms for Ensuring BWC Compliance

Country/Program	Characteristics
Australia	
Defence Science and Technology Organisation	2007 funding[a]: $2.65 million (AUD), 8% extramural 2007 staff[a]: 35 Annual, informal project level oversight by multi-agency Biodefence Advisory Committee Prior and concurrent oversight of projects, can trigger formal interdepartmental review Green-light[b] Individual awareness and reporting Personnel training/education, code of conduct
Canada	
Defence Research and Development Canada	2006 funding[c]: $7.1 - $9 million (CAD), ? extramural 2006 staff: ? (approx 250 at DRDC-Suffield, not all for biodefense) Biological and Chemical Defense Review Committee group of non-governmental experts conducts annual audit of R&D program, reviewing all government and contractor R&D projects, facilities, training, and doctrine Green light[b]
Germany	
Bundeswehr Medical Office	2007 funding[a]: €11.4 million, 30% extramural 2007 staff[a]: 97 No classified research No formal compliance review Prior internal budgetary review of projects Scientific review of projects by Scientific Council that includes civilians and foreign nationals Regular monitoring, inspection, reporting by state-level civil authorities Parliamentary reports and declarations Public notification of all medical R&D projects
Ministry of Interior	2007 funding[a]: €44 million, all extramural Not reviewed at this meeting
United Kingdom	
Ministry of Defence - Dstl	2007 funding[a]: £55.4 million, 15% extramural 2007 staff[a]: 227

	Informal, individual and sub-ministerial level review of government and contractor projects Policy and legal guidelines under development Advice or review by Counter-Proliferation and Arms Control Directorate can be requested Informal consultation with Foreign and Commonwealth Office as needed Green-light[b] Training and education of personnel
Home Office	2007 funding[a]: £7.1 million, 90% extramural Not reviewed at this meeting, may adopt MOD-Dstl guidelines
United States	
Department of Defense	2007 funding[d]: $913 million, ? extramural 2007 staff: ? Centralized departmental level monitoring and oversight by a Treaty Manager (post-hoc) Sub-departmental level compliance review of government and contractor activities following general guidance Sub-departmental certification of compliance and submission of annual project reports to Treaty Manager Treaty Manager submits report to departmental Compliance Review Group, which meets to review projects upon request Project compliance certified as necessary by the Under Secretary AT&L Informal consultation with State Department, other agencies Green light[b]
Department of Homeland Security	2007 funding[d]: $136 million, ? extramural 2007 staff: ? Routine, formal, structured process Sub-departmental compliance review of all government and contractor activities Department level Compliance Review Group issues compliance determinations for all projects, reviewing any project that raises compliance concern prior to issuing determination Prior and concurrent review, re-review as needed Decision archive maintained Informal consultation with State Department, other agencies Red light[b] Training and outreach program
Intelligence Community	2007 funding and staff: ? Compliance system under development May involve ODNI level oversight and component level review Review may be informal, following common guidelines May involve prior review May consult with State Department, other agencies
Other Government Agencies (DHHS, NSF, EPA, USDA)	2007 funding[d]: $1907 million, ?extramural Not reviewed at this meeting

Footnotes:

a. from annual BWC Confidence Building Measure submission

b. Green light – projects automatically commence unless put on hold or terminated
Red light – projects generally must receive approval prior to commencing

c. from "Federal Funding for Biological Weapons Prevention and Defense, Fiscal Years 2001 to 2009" Center for

Arms Control and Non-Proliferation, April 15, 2008 (revised May 27, 2008), at http://www.armscontrolcenter.org/policy/biochem/articles/fy09_biodefense_funding/

d. based on CRTI 2005-2006 Annual Report; may not reflect all biodefense spending. At http://www.css.drdc-rddc.gc.ca/crti/publications/reports-rapports/ar05_06_pt1-eng.pdf;

Part I – Summaries of BWC Compliance Mechanisms

This section summarizes the mechanisms and processes used by several government departments and agencies in Australia, Canada, Germany, the United Kingdom, and the United States to ensure their compliance with the BWC.

Australia – Defence Science and Technology Organisation

Australia's biodefense effort began in the 1990s. Although it has expanded in recent years, it remains small (approximately 30 people).

The Australian government established a Biodefence Advisory Committee as an informal oversight mechanism to ensure compliance of the Defence Science and Technology Organisation (DSTO) biodefence program with the provisions of the BWC and associated domestic legislation. The Committee includes representatives from the Departments of Foreign Affairs and Trade, the Attorney General, Health, and Defense (Policy), as well as a senior academic life scientist. Although the Committee is advisory only, if any member raises compliance issues or concerns, the concerns can be brought to the relevant agency for discussion and, if necessary, can be brought forward for formal interdepartmental review. In operation, the Committee meets once a year to preview proposed DSTO biodefence projects to ensure that they are consistent with the BWC, and to review ongoing DSTO projects to ensure that they remain consistent with the Convention. The operation of the Committee is being reviewed to assess whether it should include similar oversight of DSTO's chemical defense activities, and to determine the scope of the activities that fall under the category of "life sciences."

More recently, the Australian government has been working with DSTO biodefense scientists to develop drafting elements for a workplace code of conduct. The code would establish certain requirements in order to ensure that DSTO biodefense scientists comply with all relevant obligations, legislation, regulations and oversight mechanisms, and to prevent activities which would deliberately or inadvertently assist in the development of biological weapons. The elements include:

- awareness of international obligations under the BWC;
- awareness of national laws and regulations related to these obligations;
- awareness of the various regulatory and oversight mechanisms applicable to DSTO and its biodefense research program;
- a personal commitment by all biodefense scientists employed by DSTO to comply with all international obligations, national laws and regulations, and applicable regulatory and oversight mechanisms;
- awareness of the dual-use nature of biological materials, equipment and knowledge, and a personal commitment by all biodefense scientists employed by DSTO to neither deliberately nor inadvertently assist anyone in any BW proliferation or bioterrorism activity; and
- a personal commitment by all scientists employed by DSTO to report any issues or activities that may be relevant to compliance with the BWC, national laws and regulations, and oversight mechanisms to their senior manager.

The code is expected to be finalized and promulgated in the months ahead and may also incorporate relevant aspects of compliance of the DSTO chemical defense program with the provisions of the Chemical Weapons Convention.

Canada - Defence Research and Development Canada

Defence Research and Development Canada (DRDC) is a special operating agency of the Canadian Department of National Defence (DND). It is responsible for ensuring technological preparedness and relevance for the DND, the Canadian Forces, and the broader national security environment. Its Centre for Security Science, a joint effort between DND and Public Safety Canada, takes a leading role in coordinating, funding and administering biodefense research, development, testing and evaluation projects with a wide range of federal partners, academia, and private industry. The Centre also carries out technology forecasting, risk assessment and capability-based process management. Most DRDC biological and chemical defense research and development efforts are actually executed by its research center in Suffield. The number of staff at DRDC-Suffield roughly doubled between 2002 and 2007 to approximately 260 individuals.

Compliance oversight of DRDC biodefense work has its origins in the Barton Report ("Research, Development and Training in Chemical and Biological Defence Within the Department of National Defence and the Canadian Forces: A Review by William H. Barton," 31 December 1988"). Barton was mandated to review the chemical and biological defense program within DND and the Canadian Forces to "ensure that all research, development and training activities … are, in fact, defensive in nature." The Barton Report served to guide the subsequent development and implementation of DND policies that would provide:

- a clear statement of principles that all research, development, and training activities are confined to defensive purposes;
- assurance that all such activities are necessary;
- assurance that quantities of agents are limited to the amounts needed for legitimate research, development and training activities;
- direction for the safe preparation, transport, storage, use and disposal of agents and waste material; and,
- a "suitable arms-length mechanism to review policies and procedures on an ongoing basis to ensure that any work conducted remains defensive in nature."

The "arms-length mechanism" developed by the DND is the Biological and Chemical Defence Review Committee (BCDRC). The Committee is mandated to conduct an annual audit of the research, development, and training activities in biological and chemical defense undertaken by DND and its contractors in order to ensure that they are defensive in nature and are conducted in a professional manner and pose no threat to public safety or the environment. The Committee is briefed on every biological and chemical defense project conducted by DND, including classified projects. It issues a public annual report on the unclassified portion of the program summarizing its findings and providing recommendations.

The BCDRC comprises three non-governmental experts supported by an executive officer responsible for all procedural, reporting, coordination, and administrative matters. The Committee chairperson is appointed for a five-year term by the Deputy Minister of National Defence and the Chief of the Defence Staff from among the existing Committee members. The Chairperson in turn appoints new members as necessary based on nominations solicited from

several Canadian scientific societies. All members of the Committee possess a Secret Security Clearance.

The BCDRC annual review includes:

- visits to and examination of the facilities, processes, guidelines, material holdings, reports, records, and research and development programs and contracts of the chemical and biological defense program at DRDC Suffield and other relevant Centres;
- an annual briefing on the biological defense program, including contractor and industry executed programs;
- review of the formulation of the annual DRDC chemical and biological defense research and development program;
- review of the Joint NBC Company and the Canadian Forces Health Services/Health Services Operations and research and development priorities;
- review of the Global Partnership program jointly run by DND and the Department of Foreign Affairs and International Trade (DFAIT);
- review of other departmental activities, including chem/bio training and doctrine and the work of the International Committee;
- audit of collaborating organizations with transferred holdings and review of research contracts; and
- in-camera discussion with research staff and opportunities to talk off-site.

The Committee serves as an oversight mechanism rather than a compliance mechanism. DFAIT examines the work of the Committee, and works with other government departments to conduct a compliance review as part of the preparation of Canada's annual Confidence Building Measure submission to the BWC.

Federal Republic of Germany - Bundeswehr

Division IX of the Bundeswehr Medical Office is responsible for most military biodefense research and development activities in the Federal Republic of Germany. The Bundeswehr does not conduct or support any classified biodefense research. It segregates medical research (conducted or funded by the Institute of Microbiology in Munich) from research on protective equipment (conducted or funded by the Research Institute for Protective Technologies and NBC Protection in Munster). Civilian biodefense research and development activities are largely conducted or funded by the Ministry of Health and the Ministry of the Interior and are not discussed further in this report

Germany has enacted a number of laws that establish the context within which bioweapons-related activities are conducted. These include: the War Weapons Control Act of 1961, which enacts Article I of the Convention; the Foreign Trade and Payments Act of 1961, which regulates exports of certain biological materials and dual-use equipment; the Biological Material Regulations; the Genetic Engineering Act of 1990, which regulates the handling of genetically-modified organisms; the Infections Protection Act of 2001; and the Animal Ethics Act. Formal authority for implementation of the latter three acts rests with the states in which research is performed rather than with the federal government.

The Bundeswehr does not have a formal BWC compliance review process as there are relatively few (15 – 20) biodefense projects in any given year. Rather, it relies on a variety of internal, legal, parliamentary, external, and other control mechanisms to ensure that its activities

remain compliant with the Convention. Internally, the Ministry of Defence has budgetary oversight for and conducts budgetary reviews of all biodefense projects conducted or funded by the Bundeswehr prior to their financing and execution. In addition, all research proposals are subject to scientific review by a Scientific Council comprised of the Head of Division IX, 3 civilian scientists, 3 heads of military research institutes, and foreign nationals. These internal reviews, though not legal in nature are conducted in the legal context discussed above. If there is considerable potential that the research findings of a given project could be abused, the project is unlikely to be funded.

Legally, Bundeswehr biodefense projects are subject to regular state monitoring by civil regulatory authorities in accordance with the Genetic Engineering, Infections Protection and Animal Ethics Acts. Parliament is provided with an annual declaration of all projects, including biodefense projects, that involve genetic engineering. Externally, Germany submits annual BWC Confidence Building Measure reports to the United Nations, publishes the topics, goals and content of all medical research and development projects on the Bundeswehr website, and regularly publishes project results nationally, internationally, and at scientific congresses. In addition, all biosafety level 3 laboratories must register with the Ministry of Health and are inspected by the governments of the states in which they reside. All Bundeswehr (and all other) facilities working with genetically modified organisms are also inspected by state authorities on an annual basis.

United Kingdom - Ministry of Defence

The Defence Science and Technology Laboratory (Dstl) in Porton Down is the only site in the United Kingdom with a substantial portion of its resources devoted to biodefense research and development programs. The biodefense program at Dstl Porton Down derives from the Defence Microbiology Division of the Chemical Defence Establishment, which was established in 1979 when about a dozen individuals were transferred from the Ministry of Defence (MOD) Microbiological Research Establishment (MRE) to the Chemical Defence Establishment (the rest of MRE was transferred to the civilian Public Health Laboratory Service). Since it was established in 1979, the biological program at Dstl has grown approximately 20-fold. Dstl Porton Down receives most of its funding from the MOD, with additional funding from the Home Office for Counter-Terrorism, which is the lead office for civilian biodefense research and development. Depending on the year, from 25 to 40% of this funding has been spent on extra-mural contracts with academia and industry.

The Director of Chemical, Biological, Radiological and Nuclear (CBRN) Policy is responsible for overall biodefense policy within the MOD. Biodefense research goals and objectives are determined by the Research Acquisition Organisation within the MOD Science Innovation and Technology branch. The CBRN Research Director is responsible for managing the planning, contracting and delivery of the research program. There are four principal areas of work in the biodefense program: hazard (threat or risk) assessment, detection and diagnosis (which includes aerosol and modeling studies), protection and contamination control, and medical countermeasures. The UK views the first area as the one where compliance issues become most acute. Hazard assessment is often driven by intelligence and is thus difficult to discuss in public.

The Counter-Proliferation and Arms Control (CPAC) Directorate of the Defense Intelligence Staff determines MOD policy on arms control, including BWC compliance. However, there is currently no formal structure or process for BWC compliance review of MOD biodefense

projects. Instead, Dstl research scientists generally consult with Dstl's own arms control and non-proliferation advisor(s) as needed to obtain advice on whether a project is treaty compliant. If necessary, CPAC and the MOD Directorate General Legal Services can be asked for their advice, as can the Foreign and Commonwealth Office (FCO) legal advisers, and the FCO Counter Proliferation Department and Arms Control and Disarmament Research Unit. These steps occur only rarely. In theory, an issue can be raised for higher level review at the Ministerial level, up to and including the Prime Minister.

In response to requests from Dstl scientists, the MOD has been working for the last several years to prepare clear written guidelines for BWC compliance that codify existing approaches and practices. Although the guidelines would formally apply only to MOD funded activities, the Home Office and other government departments have expressed interest in the possibility of adopting the guidelines once they are completed. The main objectives of the new policy guidelines are to:

- provide guidance on biodefense projects, including joint international projects;
- ensure the work is consistent with UK interpretations of the BWC and associated treaties;
- provide guidance on relevant domestic law that implements UK obligations; and
- demonstrate that the MOD has appropriate guidance in place.

The guidelines will incorporate legal guidance on interpreting Article I of the BWC, drawing on the negotiation record and including discussion of what the terms "prophylactic, protective or other peaceful purposes" mean. The guidelines will set out procedures and responsibilities for assessing BWC compliance. The MOD, and Dstl in particular, will also be responsible for reviewing the extramural projects it funds against the BWC and for requesting advice from CPAC, as the first point of contact, on a case by case basis as required. Wider departmental consultation will also be available as needed. The onus will remain on individual scientists to understand the requirements for BWC compliance, determining whether review is warranted, and requesting advice or review if necessary.

United States - Department of Defense

The Department of Defense (DoD) plays a major role in national biodefense efforts. While DoD efforts focus primarily on defending the warfighter and the warfighting capabilities of the military, DoD biodefense efforts also have applications for civilian biodefense, particularly in the realm of medical countermeasure development.

DoD sees treaty compliance as a departmental and sub-departmental level responsibility. DoD Directive 2060.1 ("Implementation of, and Compliance with, Arms Control Agreements," 31 July, 1992, updated and re-issued 9 January 2001) establishes as DoD policy that 1) "all DoD activities shall be fully compliant with arms control agreements of the U.S. Government;" and 2) "implementation of, and compliance with, arms control agreements shall be carried out so as to avoid the compromise of national security information." The Directive applies to all organizational entities (Components) within the Department.

Directive 2060.1 assigns the Under Secretary of Defense for Acquisition, Technology, and Logistics (AT&L) as the responsible official for overseeing the implementation of, and providing guidance for, "planning and execution throughout the Department … to ensure that all DoD activities fully comply with arms control agreements." The Under Secretary AT&L is further

responsible for ensuring, in coordination with the Under Secretary of Defense for Policy, the Under Secretary for Personnel and Readiness, and the Comptroller, that DoD Components "plan, program, budget, and allocate resources, including personnel, necessary for arms control agreement implementation and compliance," and for establishing a DoD working group to monitor and coordinate DoD arms control planning, programming and budget issues.

In a major change from the original Directive, the 2001 re-issue created the position of Treaty Manager, to be designated by the Under Secretary AT&L, "as required, … for oversight of implementation and compliance for each existing and prospective arms control agreement covered by this Directive." At present, the Treaty Manager for the BWC is the Principal Deputy Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs (PDATSD(NCB)) within the Office of the Under Secretary. In addition to the BWC, the PDATSD(NCB) is responsible for implementation and oversight of the Chemical Weapons Convention, the nuclear Non-Proliferation Treaty, and several other arms control agreements.

Each DoD Component is responsible for ensuring its own compliance with the BWC according to general procedures and guidance issued by the Under Secretary AT&L for planning and budgetary purposes and, as appropriate, according to coordinated military guidance provided by the Chairman of the Joint Chiefs of Staff. The components are also responsible for ensuring that they do not contract with others for illegal activities, including activities prohibited by arms control agreements. Common criteria for assessing compliance that apply across all DoD Components have not been established. Rather, each Head must "establish and execute, as required, plans and detailed procedures applicable within their respective Components for implementation of, and compliance with, arms control agreements." The components certify their compliance with applicable arms control agreements to the Treaty Manager. The Heads are also responsible for providing, "as required, periodic reports advising the Under Secretary of the arms control implementation and compliance status of activities under the purview of the Component," and for designating, as required, an "implementation and compliance review manager" for each arms control agreement.

The reports from the DoD Components are submitted annually to the Treaty Manager in response to a data call. All biological-based activities are to be reported, including all activities at any stage of research and development, located at any DoD facilities (even if conducted by a different government agency), or receiving any DoD funding. To facilitate this process, the Treaty Manager provides the DoD Components with a list of relevant activities that should be reported, including projects that use chemical or biological weapons agents or simulants, actual or simulated chemical or biological weapons munition bodies or dissemination devices, and chemical or biological-based law enforcement or riot control technologies. It also includes projects involving contamination avoidance, detection, identification, protection, decontamination, destruction, medical treatment, threat assessment, modeling, and simulation. The reports are to include an explanation of why each program or activity is compliant with the Convention.

The Treaty Manager compiles all of the information received, reviews the data, clarifies ambiguous information, and provides the results to a BWC-specific Compliance Review Group (CRG) for review. The reporting of data does not constitute approval of the reported activities by the Treaty Manager or the CRG. Under Directive 2060.1, CRGs for each arms control agreement are established, as necessary, by the Under Secretary AT&L. They are chaired by the Treaty Manager and include members provided by the Under Secretary of Defense for Policy, the DoD General Counsel (who is responsible within the Department for legal interpretation of arms control agreements), and the Chairman of the Joint Chiefs of Staff. The

purpose of the CRGs is “to monitor compliance of all DoD activities and to coordinate DoD guidance on issues arising from questions of compliance.”

The BWC CRG is convened on an as-needed basis. The CRG can be convened upon the request of a DoD Component (e.g. to seek clarification of a BWC interpretation or request to conduct activities related to the BWC), or upon the request of the Treaty Manager or any member of the CRG (e.g. to raise concerns that require review or investigation, or to discuss media concerns, the data call, or BWC Review Conference negotiations). In practice, the Treaty Manager will try to resolve any compliance concerns through consultation with the relevant Component and its compliance review officers before deciding to convene the CRG.

When the CRG is convened to consider the activities of an individual CRG Component, the affected Component has the right to express its view to the CRG. After consultation with the CRG regarding specific DoD planned activities, the CRG Chair recommends an arms control agreement compliance certification to the Under Secretary AT&L, with the coordinated rationale of the CRG and including any separate views of Components having equities in the matter. The Under Secretary has the ultimate authority to certify that specific planned activities are in compliance with arms control agreements. On other compliance issues requiring resolution, the CRG chair provides recommendations for resolution to the Under Secretary, again with coordinated rationale and including any separate views of Components. Any compliance issue concerning disclosure of classified military information to a foreign government or international organization is to be resolved in accordance with DoD Directive 5230.11 (“Disclosure of Classified Military Information to Foreign Governments and International Organizations,” 16 June 1992). If DoD is not the original disclosure authority, then issues concerning disclosure are coordinated with the originator.

United States - Department of Homeland Security

The Department of Homeland Security (DHS) plays a major role in national civilian biodefense efforts. The Department recognizes that concerns have been raised about potential non-compliance of some of its activities with the BWC, as well as about their potential to foster a biological “arms race” or enable the proliferation of biological weapons material and know-how. Concern has particularly focused on threat characterization projects, which can sometimes involve sensitive research into the offensive aspects of biological agents and which are sometimes classified.

Like other US federal departments and agencies, DHS sees treaty compliance as a departmental level responsibility. DHS Management Directive 6300 (“Compliance With, and Implementation of, Arms Control Agreements,” 26 August 2005) establishes as DHS policy that 1) all Department Subcomponents and Agencies and their activities, and all governmental and non-governmental entities directly engaged in work to support the Department at the federal level, “shall comply with and implement the arms control agreements of the United States;” 2) that “compliance with, and implementation of, arms control agreements shall be carried out so as to avoid the compromise of national security information;” and 3) that “all relevant research, development, and acquisition projects shall be assessed for arms control compliance at inception, prior to funding approval, whenever there is significant project change, and whenever in the course of project execution an issue potentially raises a compliance concern.”

DHS has established a formal structured process for analyzing and certifying that its research, development, and acquisition activities are compliant with US treaty commitments. At the

highest level, a departmental-level Compliance Review Group (CRG) is responsible for monitoring compliance of all DHS activities, providing guidance on issues arising from questions of implementation and compliance, and making compliance determinations on projects that could potentially raise compliance questions, specifically including all biological countermeasures activities. The CRG considers not only treaty compliance per se, but also discusses project risks more broadly and whether classification of a given project is warranted. Every member of the CRG must agree with each compliance determination, and the determinations must be approved by the Deputy Secretary of Homeland Security on behalf of the Secretary. If the CRG is unable to resolve a treaty compliance issue, the CRG Chairperson recommends a compliance determination to the Secretary of Homeland Security, including any dissenting views of CRG members or Department subcomponents and agencies that have equities in the matter. Ultimate authority for compliance determinations is thus vested in the DHS Secretary. As of February 2008, no issue had been forwarded to the Secretary for a final determination.

The CRG is chaired by the Deputy Secretary of Homeland Security or his designee, and includes the General Counsel, who is the responsible authority within the Department for legal interpretation of arms control agreements, the Assistant Secretary for Policy, the Under Secretary for Science and Technology and other participants as appropriate (e.g., Chief Medical Officer, Under Secretary for Intelligence and Analysis). The Under Secretary for Science and Technology acts as the Executive Secretary for the CRG, and is responsible for ensuring that any issue that reasonably raises a compliance concern is brought to the CRG for compliance determination, for providing technical and administrative support to the CRG, and for facilitating its activities. The CRG is supported in this role by the Assistant General Counsel for Science and Technology. The heads of all DHS Components and Agencies must coordinate with the Executive Secretary before taking any action that “could reasonably raise an issue of DHS compliance with an arms control agreement. When there is doubt whether clearance or resolution is necessary, it shall be sought.” They must also provide quarterly reports on all activities that have been the subject of a Departmental certification.

The Under Secretary for Science and Technology has established a Compliance Assurance Program (CAP) Office, led by the Compliance Assurance Program Manager, which acts as the Executive Secretariat of the CRG. The CAP Office is responsible for conducting rigorous, systematic, and documented reviews and analyses of all relevant research, development and acquisition projects of the Department according to DHS policy, for coordinating legal and policy assessments with legal staff and compliance program management, and for preparing arms control compliance assessments and recommendations on each project for the CRG. As mandated by Management Directive 6300, written summaries of CAP findings and recommendations are prepared, reviewed, approved, and archived in a database. The CAP Office currently reviews approximately 150 projects (including both paper studies and laboratory experiments) annually.

CAP compliance assessments incorporate programmatic, legal, policy and regulatory considerations. At the programmatic level the CAP Office elicits relevant information from executing organizations (e.g., national lab, university, private institution, etc.). For this purpose, the executing organization must submit a completed BWC checklist and a project summary. The BWC checklist contains a series of specific yes/no questions designed to elicit all relevant treaty and dual-use information, including whether:

- the project involves one of the seven categories of "experiments of concern" listed by the National Science Advisory Board for Biosecurity (NSABB) for use in identifying potential "dual-use research of concern;" [1]
- the intent of the project, i.e. will it be involved in any way with the development, production, etc. of a biological weapon(s);
- the project involves the use of select agents or toxins;
- the project involves the use of recombinant or synthetic DNA; and
- the project uses specialized facilities and equipment, including high or maximum level biosafety containment laboratories, fermenters, aerosol test chambers, or any agent dissemination means.

The project summary provides more detailed programmatic and technical information about the project, including:

- its title and objective;
- its specific rationale – including whether the project is based on any specific open-source or intelligence information (this could include cognizable threats arising from discoveries reported in the scientific literature, if weaponizable);
- a description of the scientific/technical approach;
- the project level (e.g. basic research, applied research, development, etc.);
- the project status;
- the names of any biological agents, toxins, toxic chemicals or novel reagents used in the project, their quantities (if toxins or toxic chemicals), and their disposition;
- a description of any use of bioreactors, fermenters and/or aerosol test chambers in the project; and
- the types, quantities, and disposition of any dissemination means used in the project, and the rationale for their use.

According to the Compliance Assurance Manager, the CAP Office is proactive in obtaining this information. These materials are then subject to legal, policy, and regulatory review by expert analysts in the CAP Office; any questions that arise during this review are resolved with the submitter.

The legal review is guided by considerations of national and international law, relevant precedent, treaty interpretation, and customary law and practice. It utilizes the following BWC-focused assessment criteria:

- whether the project is clearly for a prophylactic, protective or other peaceful purpose;
- whether the types and quantities of biological agents or toxins used are consistent with and justified for the intended prophylactic, protective or other peaceful purpose; and,
- whether the project includes any weapons, equipment, or means of delivery designed to use agents or toxins for hostile purposes or in armed conflict.

[1] The NSABB identified seven categories of information, products, or technologies that, if generated by life sciences research, might define that research as being "dual use research of concern." See National Science Advisory Board for Biosecurity, "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," at http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

Policy considerations include relevant Presidential decisions, White House guidance on related activities, input from other agencies as appropriate, and considerations of whether a project raises significant perceptual concerns about compliance or is otherwise "too risky" to be worth pursuing even if technically compliant. Finally, the CAP Office also reviews projects for compliance with US regulatory requirements, such as the Select Agent rules, human subjects and animal research rules, and biosafety requirements.

Based on its review and analysis, the CAP Office bins projects into one of three categories for CRG consideration:

- Category 1 projects do not, in the opinion of the CAP or the Science and Technology General Counsel, raise any compliance concerns. They do not involve NSABB "experiments of concern" and review of the project summary identifies no dual-use issues.

- Category 2 projects are those that might reasonably raise perceptions of a compliance issue but do not involve NSABB "experiments of concern." Projects would be classified as category 2 if, for example, review of the checklist or summary identified a significant dual-use issue(s), the project is expected to generate data on critical vulnerabilities, or the project involves studies of biological agent production or dissemination. The use of certain specific equipment or facilities will automatically generate a minimum classification of Category 2.

- Category 3 projects are those that might reasonably raise perceptions of a compliance issue or that involve NSABB "experiments of concern," or where the types and quantities of biological agent(s), the experimental equipment, or the procedures used or activities conducted could raise questions about intent and purpose. All projects involving "experiments of concern" are automatically classified as Category 3, as are most projects involving a Select Agent(s) or significant quantities of an agent. Category 3 determinations based on types and quantities, equipment, and procedures are made on a case-by case basis rather than according to pre-specified criteria or guidelines.

Every project reviewed and assessed by the CAP is submitted to the CRG, which meets two or three times a year (or more often if required) to review the projects and make compliance determinations. Project summaries of all cases are provided in advance. Category 1 projects are provided to the CRG in a read-ahead book. The CRG is specifically briefed on all Category 2 projects by the compliance officer. For Category 3 projects, the CRG is briefed by both the compliance officer and the principle investigator or research program manager for the project. The CRG does not normally undertake significant review of Category 1 projects but can decide to elevate the project classification or otherwise specifically review a Category 1 project before making a compliance determination. The CRG does specifically review each Category 2 and each Category 3 project prior to making a compliance determination. In the case of Category 3 projects, each CRG member must sign the compliance determinations.

Generally, no work may be performed on a project until it has received CRG approval. However, if a DHS Subcomponent or Agency feels that a Category 1 project is time-critical, the compliance officer will recommend that CRG members allow the project to proceed subject to subsequent CRG approval. Regardless of category, once the CRG has approved a project the program manager is provided with a written compliance determination letter for the project which s/he must keep on file. The letter includes an injunction that the project must be re-reviewed if any significant changes are made, as per Management Directive 6300.

Finally, the Under Secretary for Science and Technology has established a training and outreach program within the CAP Office to inform DHS officials, scientists, and contractors about the Department's arms control responsibilities, policies, and processes. As part of this training and outreach, DHS informs its researchers and contractors that unless they are engaged in a sanctioned activity (i.e., an activity which has gone through the DHS compliance review process), they are potentially in violation of US law (the BWC is codified into national law at 18 U.S. Code Section 175).

United States - Intelligence Community

The US Intelligence Community (IC) is expanding its life sciences research activities, most of which are or will be classified. The National Counterproliferation Center within the Office of the Director of National Intelligence (ODNI), established in early 2005, is currently developing an overarching compliance review framework for classified life science research sponsored by the Intelligence Community.

The ODNI is reviewing the compliance mechanisms used by DHS and DOD, as well as processes used previously within the IC, and will adopt best practices from these mechanisms. The ODNI aims to design a rigorous and flexible compliance review process that can be used consistently across the multiple Departments and Agencies that comprise the IC for activities funded via the National Intelligence Program and the General Defense Intelligence Program, the primary funding mechanisms for non-tactical IC projects. The ODNI has established four guiding principles:

1. IC - funded research must comply with US international agreements;
2. compliance review should not unduly impede or slow the research process;
3. compliance determination should be performed at a high level; and
4. the special circumstances of IC-funded research must be considered.

The ODNI anticipates that the review process will likely be *ad hoc* in nature because there are relatively few programs requiring review. Projects would likely be submitted for review prior to the start of execution. The framework currently envisions that the Deputy Director of National Intelligence would hold ultimate authority for resolving complex compliance issues. The Deputy Director could elevate an issue to the level of the Director if necessary.

Part II – Summary of Discussion

A wide variety of mechanisms for ensuring that a nation's own biodefense research and development activities comply with the Biological Weapons Convention were presented. These mechanisms differ in such aspects as their degree of formality; whether they assess individual projects, programs, or both; the primary locus for such assessment; and the degree to which independent oversight is exercised. Some rely primarily on self-determination of compliance by the individual investigator; others adopt a more formal review process involving individuals not directly engaged in the research and development activities. However, all are based on certain shared assumptions: that biodefense research and development activities must be compliant with the BWC and other treaty obligations; that such activities can and sometimes do raise compliance concerns among outside observers, both at home and abroad; that some activities could inadvertently cross into areas of non-compliance with the treaty; and that compliance review mechanisms can help governments prevent inadvertent non-compliance within their own biodefense research and development programs, thereby providing internal, and perhaps external, reassurance that a nation is complying with the BWC.

Discussion centered on two related questions: 1) how to develop oversight and review processes that can ensure that one's own biodefense activities are and remain BWC compliant; and 2) whether and how compliance processes can be designed so as to gain external legitimacy and provide outside observers (other nations, civil society, the general public) with assurance of Treaty compliance.

With regard to the second question, participants noted that enhancing the confidence of outside observers in a State's compliance with the BWC can be a formidable challenge. Some participants felt that compliance review processes could help generate confidence and that the institutionalization of such processes within countries should be promoted. It was argued that, even if one doesn't have much faith in the process of a given country, outside observers would nonetheless gain more insight into that country's activities if it had a compliance review process in place than if it did not. Some felt that the value of a compliance review process would be increased if it were backed by national criminal law, but others disagreed that this would be the case for every nation.

The discussion made clear that generating external legitimacy and confidence requires more than just having a compliance review process in place. External observers will also weigh the context within which the process exists. Factors such as whether the process is seen as encompassing all relevant activities, as existing within a respected rule of law, and as actually being followed will all impact on the level of confidence that the process generates. Some participants stated that greater transparency with regard to both compliance review processes and biodefense research activities themselves is also important. Participants noted that understanding of what it means to be open and transparent differ from country to country. Thus, it was felt that more transparent governments will need to lead by example. At the same time, it was recognized that efforts to increase transparency will be complicated by the fact that there will never be complete transparency of all biodefense activities.

With regard to the first question, there was significant discussion of treaty interpretation principles and rules and of procedural issues. Three treaty interpretation principles were put forward for discussion. The first principle was that compliance assessments should proceed from the presumption that biodefense activities must be shown to be justified under the terms of

the BWC, rather than from the presumption that biodefense activities must be considered compliant unless shown to violate the terms of the Treaty. This principle neither requires nor precludes formal review and justification of every individual biodefense activity. Although the question was raised as to whether the BWC requires such a positive justification test, there was little disagreement with this principle during the discussion, and it is implicit in most if not all of the compliance processes that were presented at the meeting.

Second, it was proposed that in order to justify an activity under Article I.1 of the BWC, the activity should be shown to be both useful *and* critical for a prophylactic, protective or other peaceful purpose, the more so the greater the compliance concern. In this conception, a "useful" activity is one that aims to increase specifically the ability of a country to protect itself against biological weapons, while a "critical" activity is one that aims to do so significantly rather than only marginally. While there was general agreement among participants that biodefense activities should be shown to contribute specifically to prophylactic, protective or other peaceful efforts, there was strong disagreement with the idea of requiring a criticality test. It was felt that a criticality test would amount to a quantitative test, which would be extremely difficult if not impossible to implement in practice, and would raise the bar for approval too high. It was suggested that, if there is a justification threshold, then a threshold for what constitutes a protective purpose would be more appropriate. It was also suggested that the concept of criticality is important in one area – activities related to weaponization. This is where the question of whether an activity is justified under the BWC is most acute, and thus where the justification arguments need to be made very clear. These suggestions were not explored further during the meeting.

Participants felt that the concept of criticality is more relevant to perceptions of (non)compliance than to actual compliance determinations. Participants did not discount the importance of perceptions. Rather, it was widely agreed that perceptions are often central to the compliance issue. Thus, it was noted that justification is often "in the eye of the beholder;" that is, that the determination of whether an activity is compliant can often be subjective. Building on this discussion, participants made two additional points, not necessarily shared by everyone present. First, when performing a compliance review, it is important to consider how an activity may be perceived. Some of the compliance review processes presented at the meeting do take perceptions into account. Second, examining discrete projects in isolation is not necessarily sufficient for determining whether either the projects themselves or the larger biodefense program are compliant with the BWC. Understanding the context within which a project is occurring is also important in determining compliance. The importance of perceptions also informed the suggestion, noted above, that the concept of criticality becomes important in the case of assessing activities related to weaponization.

The discussion surrounding the issue of criticality raised the question of how the terms of Article I are interpreted during compliance review. It was recognized that this question is both complex and central to any compliance review process. To promote discussion of the question, it was suggested that compliance review processes might adopt the following treaty interpretation rule: that the development and production of a new pathogenic agent for threat assessment purposes would be inconsistent with the BWC if there is no credible evidence that any person or group has constructed such an agent.

Meeting participants responded to this proposal in several ways. First, it was suggested that when considering the credibility of evidence on the activities of a person or group, it might be important to distinguish between aspiring to create an agent and actually accomplishing the goal. The latter would be a more compelling situation. Second, it was noted that civilian

agencies, such as the National Institutes of Health and the Centers for Disease Control and Prevention in the United States, routinely support or conduct research for prophylactic, protective, or other peaceful purposes that nonetheless involves the development and production of new pathogenic agents. It was asked how such research could be accounted for and allowed to proceed under the proposed rule. In response, it was suggested that perhaps it is not possible to come up with strict functional treaty interpretation rules, and that the solution to this problem is to be as transparent as possible. Third, it was noted that the proposed rule leaves out consideration of the types and quantities of the agents involved, which under the terms of the BWC must be consistent with prophylactic, protective, or other peaceful purposes. For instance, producing tens of kilograms of a new agent would seemingly have no justification while producing gram quantities might. Consideration of the physical form (e.g., relatively dilute liquid slurry versus highly concentrated fine particulate dry powder) is also important. Others, however, held that information about types and quantities will be less useful as a compliance indicator in the future.

The third treaty interpretation principle put forward for discussion was that there should be independent review and assessment of biodefense research and development activities for compliance with the BWC. There was significant disagreement among meeting participants on this matter. Many felt that formal interagency compliance review is neither necessary nor feasible. According to these participants, such review is not necessary because interagency technical review of projects generates transparency that helps prevent violations, because compliance is embedded in the culture of government agencies and potential violations would be noticed and called out, and/or because there is already significant, albeit informal, interagency contact which would be used when questions or concerns arose. These participants also argued that interagency review is not feasible because it would add unacceptable delays and complexity to the review process and would be too resource intensive for the external agency or agencies charged with conducting the review.

Other participants suggested that interagency review should not be done as a matter of course, but that there should be a formal interagency process for projects that closely approach the line between compliance and noncompliance. These participants argued that a focused review process such as this would help ensure careful scrutiny of the few projects that raise potential compliance concerns without being overly burdensome or costly. These participants also argued that agencies have an inherent conflict of interest when it comes to reviewing their own projects and that reliance on informal contacts has not always ensured that projects receive the level of review they require.

There was widespread agreement among the participants that the meeting was very useful, both in terms of the information shared and the ensuing discussion. The co-sponsors believe that there would be great value in further broadening such information exchanges and discussions of the mechanisms used by nations to ensure that their biodefense activities comply with the BWC.

Appendix – Participant List

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