# 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

30 July 2015

English only

**2015 Meeting**
Geneva, 14-18 December 2015

**Meeting of Experts**
**Geneva, 10-14 August 2015**
Item 5 of the provisional agenda
**Standing agenda item: cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X**

## The United States of America high containment laboratory policy

**Submitted by the United States of America**

## Introduction

1. This paper reports on United States efforts to address key issues that have been identified during discussions on international cooperation and assistance during the current BWC Intersessional Programme. In particular, it describes a recently adopted policy governing U.S. government funding for the design, construction, or enhancement of biocontainment facilities in foreign countries. This policy helps to ensure that U.S. efforts to support core public, animal, and agricultural health laboratory capacity internationally are coordinated, sustainable, and safe, while mitigating potential biosecurity and weapons of mass destruction proliferation risks. It supports the United States' commitment under the Biological Weapons Convention's (BWC's) Article X "to facilitate…the fullest possible exchange of equipment, materials and scientific and technological information for the use of…biological agents and toxins for peaceful purposes." It is also designed to be consistent with our obligation under that BWC Article to implement the Convention "in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful …biological activities…"

## Discussion

2. Recent disease outbreaks—such as Ebola, Middle East respiratory syndrome (MERS), and influenza—demonstrate the ever-present risk of the spread of infectious diseases through increased global trade and travel. These outbreaks reinforce the need for a continued and concerted international effort to build countries' capacities to effectively

mitigate the risk posed to global health security by pathogenic microorganisms. One response to this need has been a significant increase in the number of high-containment laboratories (HCLs) in operation or under construction around the world over the past decade. This is in some respects a positive development, as it often reflects improvements in laboratory biosafety standards and practices, and increased diagnostic and other capabilities needed to address the challenges of emerging infectious diseases. However, the increase in high containment laboratories also poses challenges. Many of these were outlined in *Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories*[1] (the report of an international workshop conducted in 2011), and in a working paper submitted by the United Kingdom[2], both of which informed discussions at the 2012 Meeting of Experts. These issues include:

- **Sustainability**: The operation and maintenance of a high-containment laboratory are extraordinarily expensive. Moreover, they require reliable, high-quality infrastructure (power, water, waste handling), as well as replacement parts and trained personnel for maintenance and repairs, none of which may be readily available in some areas.
- "**Fit**" in terms of national priorities and needs: Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories noted that "when contributing to a new laboratory, donor groups and national governments do not always ascertain how the new facility will complement other existing and planned infrastructure."
- **Safety**: High-containment laboratories have the potential to increase safety, but only when accompanied by ongoing training, adherence to appropriate protocols and procedures, and appropriate regulations, guidelines, or other measures to ensure oversight.
- **Nonproliferation**: While there is a legitimate need for biocontainment facilities worldwide, the inherent dual-use potential of these facilities and related equipment – as well as of the pathogens they contain and the skills developed through hands-on work – merit scrutiny in a world where terrorism and the proliferation of weapons-relevant materials, technologies, and expertise pose genuine threats.

3. In light of these challenges, both the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction and, more recently, the Global Health Security Agenda have emphasized the importance minimizing the number of facilities storing dangerous pathogens while enhancing global biosurveillance and public health capabilities. In this context it is important to recognize that scientific advances, including rapid and culture-free diagnostic methods, can reduce the need for HCLs while allowing for bioscience research to take place safely, sustainably, and securely at lower levels of containment than was previously possible.

4. The same challenges have also been a topic of discussion during the current BWC Intersessional Work Programme. The consensus reports of recent Meetings of States Parties have emphasize the importance of:

[1] Committee on Anticipating Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories; National Academy of Sciences; National Research Council. Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories. Washington (DC): National Academies Press (US); 2011 Dec 15: http://www.ncbi.nlm.nih.gov/books/NBK196155/

[2] BWC/MSP/2012/MX/WP.2: Challenges to developing international cooperation and assistance on biosafety and biosecurity: matching resources to reality - submitted by the United Kingdom.

- "The challenges associated with the provision of sustainable biosafety and biosecurity capabilities, including in low-resource settings";
- "Pursuing a long-term, sustainable and systematic approach to the provision of cooperation and assistance";
- "Improving coordination of key activities in order to enhance synergy and avoid duplication";
- "Developing national capacity to address biorisk management"; and
- Ensuring that cooperation and assistance "contributes to preventing the proliferation of biological weapons, including through building national capacity."

5. In 2013, the United States government issued policy guidance aimed at ensuring that Federal agencies' laboratory capacity-building efforts are coordinated, serve to enhance foreign countries' public and agricultural health infrastructure, and take into consideration biosecurity and proliferation risks. This policy, Guiding Principles and Assessment Process Related to the Provision of Biocontainment Facilities to Foreign Countries, known commonly as the High Containment Laboratory (HCL) Policy, recognizes that high containment laboratories are expensive to build and operate and that the highest level of containment is only required in a handful of circumstances. For those circumstances where providing an HCL might be appropriate, the policy includes a set of guiding principles for use by United States government departments and agencies that are planning to fund the design, construction, or enhancement of a biocontainment facility in another country.

6. The HCL policy also established an interagency process to share and assess proposals by U.S. government departments and agencies that plan to fund the design, construction, or enhancement of biocontainment facilities abroad. This interagency process seeks to increase transparency and coordination and to reduce duplication of effort across the federal government. In order to mitigate proliferation risks and other concerns associated with supporting biocontainment facilities abroad, the U.S. interagency process identifies and addresses concerns regarding sustainability, biosafety, biosecurity, weapons of mass destruction (WMD), and foreign policy. By focusing on these considerations, the policy reflects the emphasis in the current BWC intersessional program on taking a "long-term sustainable and systematic approach to the provision of cooperation and assistance" that takes into account "differing national circumstances," prevents biological weapons proliferation, and "reinforces defenses against new and emerging diseases."3

7. When an HCL review is conducted by U.S. government departments and agencies, five key factors are used to make a determination on a proposed laboratory. First, there has to be a demonstrated need for the biocontainment facility in a foreign country, taking into account "differing national circumstances." Second, the recipient of the laboratory or related equipment must demonstrate the commitment and ability to operate, maintain, and sustain the facility in a safe and secure manner upon its completion, consistent with the 2012 MSP's emphasis on the challenge of providing "sustainable biosafety and biosecurity capabilities, including in low-resource settings."4 Third, the recipient country must demonstrate a commitment to nonproliferation. Factors including the quality of the recipient country's export controls and adherence to the Biological Weapons Convention are included in this review. Fourth, departments and agencies also review proposals to ensure that they do not pose any other risks and that they are consistent with U.S. national interests. Finally, factors related to biological risk management are considered, including

[3] 2012 and 2013 Meeting of States Parties.
[4] 2012 Meeting of States Parties.

biosafety and physical security measures that are currently implemented or planned at the facility. A set of structured questions is used to facilitate review of these factors (see Annex).

8. The U.S. interagency assessment is intended to complement work being carried out under multilateral agreements and existing laws, policies and agency authorities, such as the Biological Weapons Convention and U.S. export control laws. We have found it beneficial to integrate HCL policy review into the existing U.S. export license review process, as it helps agencies identify and address potential proliferation risks posed by biocontainment facilities proposed for U.S. funding in the earliest phases of consideration, well before an agency needs to submit an export license for equipment and/or technology needed to build a facility. The new HCL policy illustrates that a single review process can help to ensure that international cooperation is responsive to the needs of the recipient, coordinated with other efforts, sustainable, and consistent with nonproliferation-related undertakings and objectives.

# Annex

## Questionnaire for U.S.A. government providers and planners of biocontainment facilities to foreign countries

The following list provides a general framework of questions to be considered in order to address the principles set out in the 2013 policy *Guiding Principles and Assessment Process Related to the Provision of Biocontainment Facilities in Foreign Countries*. The interagency should refer to these questions during the comment phase, after the sponsoring department or agency has provided basic program information; the sponsor should also be encouraged to consider these questions more comprehensively when initially providing information to the interagency. Sponsors may also add or revise the following questions as relevant to the specific circumstances of their project. General questions related to each of the five guiding principles are as follows:

1. Establish a demonstrated need for the high containment biocontainment facility in the foreign country.

- For what purpose will the facility be used (e.g., clinical diagnostics, reference diagnostics, research, vaccine development, etc.)?
- Is high containment laboratory (HCL) capability the only means to meet this public health need? Has the sponsoring department or agency conducted an analysis of alternatives to consider other means of achieving the requested capacity and, if so, what were the results for each alternative?
- What additional or unique HCL capability has or will be provided by this effort, which goes beyond existing host nation capability? (e.g., a higher level of biocontainment, additional facility square footage, equipment)
- Is the host nation asking for more capability than is necessary to address the needs of interest to the sponsoring department or agency, or for more capability than is required to meet the stated need? (e.g., higher BSL level, additional square footage, equipment, etc.)
- Are there other plans (e.g., with other funders) to incorporate enhanced biocontainment engineering features into this HCL that go beyond the stated need? If so, have these been carefully evaluated?

2. Establish that the recipient has demonstrated the commitment and ability to operate and maintain the facility upon completion.

- What host nation organization does or will own, operate, and oversee the functions of the proposed HCL? Has this organization committed to long-term oversight and leadership of the HCL?
- What domestic and foreign organizations will partner on, collaborate with, or fund activities at the proposed HCL?
- Does the host nation organization possess the ability to independently operate and maintain the facility in the future? Key factors that should be addressed include:
    - Quantity/quality of trained personnel (including for operations and maintenance)
    - Funding (including for operations and maintenance)

- Available safety and security infrastructure (e.g., trained personnel, physical security measures, safety and security standard operating procedures)
- Stable utilities, accessible consumables/equipment, maintenance, etc.

- Have plans for long-term sustainability of the facility been developed and evaluated?
- Has the host nation HCL, the host nation organization, or its host nation partners ever lost control or accountability of select agent material, had a significant accident or laboratory acquired infection, or suffered a breach in security?

3. Establish that the recipient's country demonstrates commitment to nonproliferation.

- Is the host nation a member of the Biological and Toxin Weapons Convention (BTWC) and the 1925 Geneva Protocol, and in compliance/seeking compliance with the obligations under these treaties[1][2]?
- Is the host nation a member of the Australia Group (AG) or has it adopted export controls similar to those of AG members[3]?
- Does the United States assess that the host nation has an offensive or defensive biological weapons program?
- Has the host nation reported to the United Nations on its implementation of UNSCR 1540[4]? If so, are gaps identified in the reporting with respect to controls on BW-relevant materials or equipment[5]?

4. Foreign policy considerations are addressed.

- Have the U.S. Department of State and the Ambassador-in-country been apprised, and are they supportive of the proposal to provide a biocontainment facility?
- Has the U.S. Department of State determined whether the host nation entity is sanctioned or is subject to export restrictions?
- Are there known sensitivities or issues with neighboring states that might be exacerbated by USG funding of this facility?

---

[1] Information on the status of a country's accession to the BWC can be found here: http://www.unog.ch/80256EE600585943/(httpPages)/7BE6CBBEA0477B52C12571860035FD5C?OpenDocument. Further details on compliance, and specifically, the country's diligence at submitting Confidence Building Measures to the BWC, can be found here: http://www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument. Information on the Geneva Protocol can be found here: http://www.un.org/disarmament/WMD/Bio/1925GenevaProtocol.shtml

[2] For specific questions or further information about BWC compliance and objectives with respect to a particular host country, please contact the Department of State's Biological Policy Staff at ISN-BPS-DL@state.gov.

[3] For a list of Australia Group participants, please see: http://www.australiagroup.net/en/participants.html. See also UNSCR 1540 compliance resources below.

[4] Matrices on UNSCR 1540 reporting for each country are available here: http://www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml. The individual country reports from which the matrices were assembled can be accessed here: http://www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[5] For a 2011 report identifying gaps in UNSCR 1540 compliance and implementation, which draws upon the reports submitted by each member country, see: http://www.un.org/ga/search/view_doc.asp?symbol=S/2011/579.

- Is or will the HCL be associated with the host nation's military or defensive biological weapons program (as permitted under the BWC)?

5. Factors related to biological risk management are considered (biosafety, security, training, local codes and regulations)[6].

- What plans are in place to archive infectious strains of microorganisms over time or for transferring duplicate archival microorganism strains to other secure facilities (i.e., will the facility be a repository or will all unused infectious materials be destroyed or transferred)? What plans are in place to archive toxins (e.g., toxins on select agent list)?
- Have comprehensive risk assessments been performed for the site to determine necessary biosafety and security features to include in the HCL?
- What physical security is or will be present surrounding the facility? (e.g., type of fence, guards, cameras, window barriers, etc.)
- What biosecurity (physical security and cyber security) measures are or will be in place within the facility at areas where pathogens and toxins are present? (e.g., cipher locks, door badges, cameras, etc.)
- What type of tracking system and protocols are or will be in place for access to and accountability of the pathogens located at the HCL?
- Is there an occupational health program in place?
- How does the host nation determine who is granted access to the facility? Does the screening protocol include access to law enforcement or intelligence reporting? What would be sufficient cause for the host nation to deny an individual?
- Have training procedures for personnel been developed and evaluated to ensure safe and secure handling of pathogens at the HCL, or are there plans for such training?
- What certification will be required of scientists working in the HCL and to what extent is training updated? What does the pipeline of trained individuals look like over the next decade to deal with attrition? Is the science education infrastructure sufficient to support the facility long term?
- What HHS and USDA Select Agent pathogens and toxins (www.selectagents.gov) does the host nation HCL possess or will the host nation HCL have on hand in the future? Does this include any select agent pathogens and toxins provided by the United States?
- Will the host nation HCL contain any export-controlled dual-use biological equipment or materials received from the United States?
- Will the HCL be seeking accreditation for clinical testing?
- Is the HCL in accordance with local codes and regulations regarding construction?

[6] The use of standardized biorisk assessments for high containment laboratory facilities and the pathogens they will hold is encouraged, although it should be noted that assessments may be not be fully internationally applicable, and discretion should be used when referring to U.S.-derived resources. Examples of resources that provide methods, tools, and information to aid laboratories seeking to implement biorisk mitigation measures include: l http://www.biosecurity.sandia.gov/BioRAM/; http://www.who.int/ihr/publications/laboratory_tool/en/index.html; ABSA's accreditation checklist; and the CWA 15793. Information about working with select agents is available at: http://www.selectagents.gov/Resources.html.

- Is the HCL in accordance with local legislation regarding the possession, transfer, and use of biological agents, if such legislation exists? If it does not exist, is the HN amenable to the development of such legislation?
- What plans are in place to contain pathogens in the event of social or political breakdown or other emergency (e.g., extreme weather event)?