

Workshop on Enhancing Transparency for Bioscience Research & Development

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Framing Paper

Background & Context

One of the key risks facing the international community is the potential for deliberate misuse of the tools of modern bioscience and biotechnology to cause harm. While democratized access to these tools offers significant potential societal benefits, their dual-use nature makes it difficult to discern whether actors are using these capabilities for peaceful or nefarious purposes. This challenge is particularly salient for the Biological Weapons Convention (BWC), which prohibits the development and use of biological weapons, and whose 187 States Parties have committed to abide by these rules. As of 2022, there is now renewed energy to discuss measures related to confidence-building, transparency, compliance, and verification—after almost three decades of negotiations and stalemate. **This political opening presents an excellent opportunity to develop and implement more effective transparency measures to assess and build confidence in compliance with the BWC regime—which will also be valuable in the current geopolitical environment. To this end, NTI | bio is initiating an effort to identify specific scientific and technical, procedural, and institutional tools and mechanisms that can enhance transparency. This will be important for reducing the risk of misperceptions among BWC States Parties about the capabilities and intentions of other nations’ bioscience research and development activities.**

NTI | bio aims to use this timely opportunity to develop recommendations for potentially effective enhanced transparency measures that can improve confidence in compliance with the BWC and foster greater trust among states.

Meeting Objectives:

- Explore options, both within and alongside the BWC, for enhancing transparency regarding state-led or -supported bioscience research and development, to identify existing and new methods for discerning between peaceful and offensive uses of bioscience and biotechnology.
- Discuss essential features necessary for a successful enhanced transparency regime that are feasible and sustainable over the long-term.
- Analyze technical and scientific, procedural, and institutional challenges and opportunities that are likely to impact the potential implementation of new transparency initiatives.
- Generate practical recommendations for measures to enhance transparency regarding BWC compliance, to build trust among States Parties regarding intentions and activities.

The recommendations developed at this meeting will inform an NTI report on options for enhancing transparency regarding bioscience research and development activities. The report will include recommendations for priority enhanced transparency measures to explore, test, and potentially establish institutionally, which will be shared for consideration at the December 2024 BWC Working Group meeting.

Defining Enhanced Transparency and its Value Proposition

There are a range of tools and structures that can assist in reducing the risk of misperceptions about the capabilities and intentions of any nation's bioscience research and development activities. At one end of the spectrum is the status quo, which is anchored by the BWC's Confidence Building Measures (CBMs). CBMs are in place to help increase transparency regarding life science research and development, and they are complemented by a voluntary peer review process that has been undertaken by a subset of BWC States Parties. However, to most, today's status quo is not sufficient to provide confidence that States Parties are complying with the BWC's prohibition on development or use of biological weapons (BW).

On the other end of the spectrum is the aspiration for a full verification regime, similar to what [VEREX](#)—an *ad hoc* committee established in 1991 to research verification measures—worked to create more than two decades ago. While there is still no verification regime in place, there is also no consensus within the biosecurity community that “verification,” as traditionally defined and understood, is practically achievable. In addition to important questions about feasibility, there are also significant political challenges to establishing a full “verification” regime. This spectrum leaves a lot of space in between CBMs and traditional “verification” for more robust transparency measures. **The tools, measures, and structures that fall in the space between CBMs and classical “verification” are what we term enhanced transparency.**

Enhanced transparency efforts can reduce the risk of misperceptions in bioscience research and development through collection and analysis of data through scientific, technical and other means; processes to gather the data; and institutions that support these processes.

Methods & Approaches for Enhancing Transparency

For the purpose of this meeting and NTI's final report, measures for enhancing transparency are grouped into three key categories: (1) technical and scientific approaches for data collection, (2) procedural approaches, and (3) institutional structures. Below is a brief overview of each category with examples and a set of key questions to guide the preparations for the upcoming workshop. In the final report, NTI will assess operational feasibility and address inherent challenges for each recommended approach.

I. Technical and Scientific Approaches for Data Collection: *Deployment of modern scientific methods and technologies to collect and analyze data that can offer meaningful insights to help differentiate between legitimate and illegal/offensive uses of bioscience and biotechnology.*

Scientific and technical methods for gathering and analyzing information can offer significant contributions to modern enhanced transparency. When leveraged effectively, these tools and methodologies can enable new and enhance existing methods for on-site assessments and remote monitoring. Due to major advances in bioscience, biotechnology, data science, imaging, artificial intelligence (AI), and other related fields over the past 20 years, there is now a vast landscape of tools and capabilities that can be leveraged for these purposes. These groundbreaking advances provide unique and novel opportunities to collect and analyze data to further enhance transparency, lowering the risk of misperceptions in life science research.

The key task when identifying scientific or technical approaches to enhance transparency is to determine *which data and other evidence, and which analytical methods, have the greatest potential utility in providing insights into whether bioscience research and development activities are benevolent or nefarious.*

Examples of potential on-site technical and scientific approaches include:

- Sampling Within Lab Spaces and In Waste Streams:
 - Analysis of Samples from Vials and Surfaces: Comprehensive sampling and sequencing of material from test tubes and laboratory surfaces, including the utilization of metagenomic sequencing for pathogen agnostic detection, can provide a means to assess the accuracy of laboratories' stated research activities.
 - Sampling of Laboratory Wastewater and Solid Waste: While modern bioscience laboratories go through extensive treatment of their effluent water to ensure that it is safe for public release, a wastewater sampling regime can shed light on research activity through metagenomic sequencing and other analytic methods.
- Reviewing Laboratory Notebooks: Analyzing laboratory notebooks, complemented by other forms of information collection including interviews with scientific researchers, can shed light on research underway within the lab.

Examples of potential off-site technical and scientific approaches include:

- Collection And Analysis of Publicly Available Information (PAI): The use of PAI when coupled with machine learning tools holds significant potential for enhancing transparency for bioscience research, though additional work is needed to address regional trade pattern differences, uneven data availability, and opportunities for integration with other data types.
 - Financial Data Flows and Inventories: Analyzing laboratory financial records and/or inventory and shipment manifests can be used to detect anomalies compared to stated ongoing research.
 - Publications: The publication of research is the bedrock for laboratory-based scientists, whether they work for a State, academic, or public institution. Utilizing AI to scan publications has the potential to yield helpful information about individual researchers and scientific research facilities.
- Remote Sensing and Imaging: Remote sensing and imaging has dramatically improved over the past two decades, in both granularity and coverage, and there are greater capabilities to analyze these data using AI methods. Remote sensing provides the opportunity to analyze and compare deliveries, movements, footprints, and gating to both stated laboratory research and design.
- DNA Synthesis Screening: DNA synthesis is widely used in bioscience research in laboratories around the world. The application of synthesis screening data to enhanced transparency is an unconventional idea that would face significant feasibility challenges, including the need to draw upon private industry data which are not currently shared. However, if such challenges could be surmounted, DNA synthesis screening data may be able to provide granularity about the type of

research being conducted in a lab that purchases DNA from external vendors. Continuous automated analysis may be able to help validate the authenticity of a stated research agenda.

II. Procedural Approaches: *Deployment of various processes to gather data, evidence, and insights by augmenting existing processes or developing new ones, either within the BWC or adjacent to it.*

Procedural approaches to enhancing transparency are the processes by which the data are collected using the scientific and technical approaches discussed above. Different procedural approaches may be needed depending whether data gathering occurs on-site or remotely, and whether it is continuous or on an as-needed basis.

Examples of procedural approaches include:

- **NGO- or other Third-Party-Led Pilot Project(s) to Explore Site Visit Modalities:** In order to create effective, fair and repeatable approaches to site visits, standard operating procedures need to be developed, tested, and validated. To develop such standard operating procedures, an NGO could partner with private industry and/or academic volunteers to experiment with site visit tactics and needs, to explore which approaches are most useful in enhancing transparency while protecting proprietary information.
- **Enhanced Voluntary Peer Review:** Within the BWC context, some states have begun voluntary peer review processes, to include document reviews, facility visits, and scientific exchanges. While the implementation of these peer reviews has yielded mixed results, building on this foundation—including through more robust data collection activities—could offer an opportunity to establish more robust transparency measures. Additionally, there may be utility in an NGO exploring additional peer review tactics and procedures, to find areas where peer reviews could be strengthened.
- **Continuous Remote Monitoring:** An independent network of satellites, and their associated imaging data streams, which could be made available to all BWC States Parties through a negotiated agreement, could allow for an unbiased and accessible platform for data collection and analysis.
- **Scientific Exchanges:** A large influence in the misperceptions of bioscience research and development can be attributed to the insular nature of some research laboratories. A scientific exchange program, where scientists are seconded to labs in other countries, can reduce misperception risks and contribute to enhanced transparency.
- **Official Inspections:** Official on-site inspections conducted on behalf of an international organization may provide the most internationally accepted approach to enhancing transparency. While establishing routine and/or challenge inspections would face considerable practical and political challenges, such a mechanism could help counter misperceptions and misinformation, and incentivize BWC compliance.
- **Enhanced Confidence Building Measures:** As stated earlier, the current status quo for CBMs has not proved sufficient to provide confidence that States Parties are complying with the BWC. While not a major step forward, incremental enhancement of the CBMs, to include updating CBM forms, can yield minor advances in enhanced transparency.

III. Institutional Structures: *Augmentation of existing institutional structures or development of new structures—either within the BWC or adjacent to it—to support needed scientific, technical, and procedural approaches.*

Institutional structures provide the lasting foundation to build and house technical, scientific, and procedural approaches. While the BWC provides a very clear and widely accepted institutional framework to house these approaches, other institutional structures and settings should also be considered. Existing structures may need to be modified, or new institutional structures may need to be developed.

Key examples of institutional structures include:

- Structures Within the UN System:
 - Enhanced Implementation Support Unit (ISU): The ISU is a historically underfunded and under-resourced support structure. The ISU, as currently resourced, would not be able to house and support additional enhanced transparency efforts. A more appropriately resourced ISU could more effectively oversee the implementation of an expanded set of activities to enhance transparency.
 - Full Structure—Organization for Prohibition of Biological Weapons: The Organization for the Prohibition of Chemical Weapons (OPCW), which is responsible for overseeing the implementation of the Chemical Weapons Convention, is more than 100-fold larger than the ISU. The creation of a larger structure with significant additional resources, analogous to the OPCW, may be required to support a comprehensive, ambitious approach to enhancing transparency.
 - Expanded Mandate of the Secretary-General’s Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM): The BWC has no mechanism to investigate either the alleged use of BW or the alleged development of BW. The UNSGM, which is distinct and independent from the BWC, is the only international mechanism to investigate the alleged use of BW. However, even with efforts in recent years to strengthen the readiness of the UNSGM for BW investigations, many gaps remain. Strengthening the capabilities for as-needed UNSGM investigations, including for allegations of nefarious research or pandemic origin investigation, can help enhance transparency. A robust and expanded cadre of experts in diverse areas of biological sciences will likely be needed, as well as a globally agreed set of reference laboratories.
- Structures Outside the UN System:
 - Open-Source Community Effort: While a structure within the UN would provide legitimacy, reaching agreement to establish such a structure is likely to be challenging. As an alternative, an external community could be developed to track and support the analysis of open-source data streams, and possibly NGO-led pilot projects to explore procedural solutions. This community could share their data and analyses with the BWC and possibly the public. Such a novel system would require a large influx of sustained resources.

Guiding Question

To guide the preparation for the meeting, please consider the following question:

What established or new scientific methods and/or technologies, processes, or institutional structures can support the collection and analysis of data to help differentiate between legitimate and illegal/offensive uses of bioscience and biotechnology? As best you can, please characterize each approach or structure and note which of the following categories it supports: (note: an approach or structure may support more than one category)

- *On-site, continuous*
- *Off-site, continuous*
- *On-site, as needed/acute*
- *Off-site, as needed/acute*

Optional Background Materials

Links to other background sources for optional read ahead materials.

[The BWC Protocol: Mandate for Failure](#)

Kenneth Ward

In this article, Ward examines the challenges and complexities behind the unsuccessful negotiations of the Biological Weapons Convention (BWC) Protocol.

[Seeking Biosecurity Without Verification: The New U.S. Strategy on Biothreats](#)

Jonathan Tucker

In this article, Tucker critically examines the 2009 U.S. strategy on biodefense and biosecurity, which lacks provisions for verification. The document outlines how this approach shifts focus from international treaties, such as the BWC, to domestic preparedness and response to biological threats. Tucker argues that the absence of verification measures weakens global biosecurity efforts by reducing transparency and international collaboration.

[Compliance Revisited: An Incremental Approach to Compliance in the Biological and Toxin Weapons Convention](#)

James Revill

In this report, Revill explores the issue of compliance within the BWC. It emphasizes that compliance involves more than just signing the treaty; it includes adherence to various obligations which have evolved due to scientific advancements.

[Signals in the Noise: Preventing Nuclear Proliferation with Machine Learning & Publicly Available Information](#)

Nuclear Threat Initiative (NTI) and Center for Advanced Defense Studies (C4ADS)

The report summarizes a pilot project between NTI and C4ADS that demonstrates the potential of machine learning and PAI in identifying high-risk nuclear trade activities. For the BWC, similar methods could be used to uncover illicit biological research facilities, dual-use biological materials trading, or unusual shipments that may be linked to bioweapons production.

Voluntary Transparency Initiatives: The Case of Peer Review Exercises in the Context of the BWC

Maria Espona

In this report, Espona examines the role of peer review exercises and other voluntary transparency initiatives within the BWC framework.

Feasibility of on-site verification

Piers Millett, Tessa Alexanian, Evan Appleton, James Diggans, Michael Montague, and Alexander Titus

This article provides an in-depth analysis of the feasibility of on-site verification for the BWC.

Through a detailed case study approach, the authors examine the effectiveness and practicality of on-site inspections in ensuring compliance with the BWC.