U.S. Government Concerns With A Compliance Protocol

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Outline

- Industry's concerns then
- Past models for verification
  - IAEA Safeguards
  - CWC Verification
- BWC
  - Relationship with past models
  - Draft Protocol
  - National Trial Visit
- Convergence of Industry and government then and now

Industry's Concerns

"…our industry has very serious concerns about a compliance protocol that includes non-challenge clarification visits. We believe that these visits are, in fact, low-threshold challenge inspections that would fail to further the legitimate aims of the Biological Weapons Convention, yet would pose significant risks to the inspected company's research and development efforts and business operations."

Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America
Carl B. Feldbaum, President, Biotechnology Industry Organization
Alexander S. Mathews, President and CEO, Animal Health Institute

Treaty on the Nonproliferation of Nuclear Weapons

- Requires nuclear safeguards measures to verify declarations through detailed nuclear material accountancy
- Some of the measures are:
  - Visual verification
  - Independent measurements
  - Containment and surveillance
  - Unattended monitoring

Chemical Weapons Convention

The Schedules of chemicals identify specific chemicals for the application of verification measures

- Inspections at S1 facilities verify:
  - Chemicals and quantities produced
  - Quantities of precursors used
  - Quantities consumed
  - Quantities shipped or received*
  - Maximum quantity stored at any time
  - Quantity stored at the end of the year

* Single small-scale facility

Chemical Weapons Convention - ii

- Inspections at S2 facilities verify chemicals produced, processed, or consumed in amounts exceeding:
  - 1 kilogram of S2A* chemicals
  - 100 kilograms of other S2A chemicals
  - 1 tonne of S2B chemicals
- Inspections at S3 facilities verify chemical production exceeding 30 tonnes
- Inspections at OCPFs verify chemical production exceeding 200 tonnes

Compare Past Models for Verification

What verification elements are common to both nuclear safeguards and the CWC?

Answer

Count critical materials

Verify that facilities are not conducting prohibited activities

Biological Weapons Convention

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

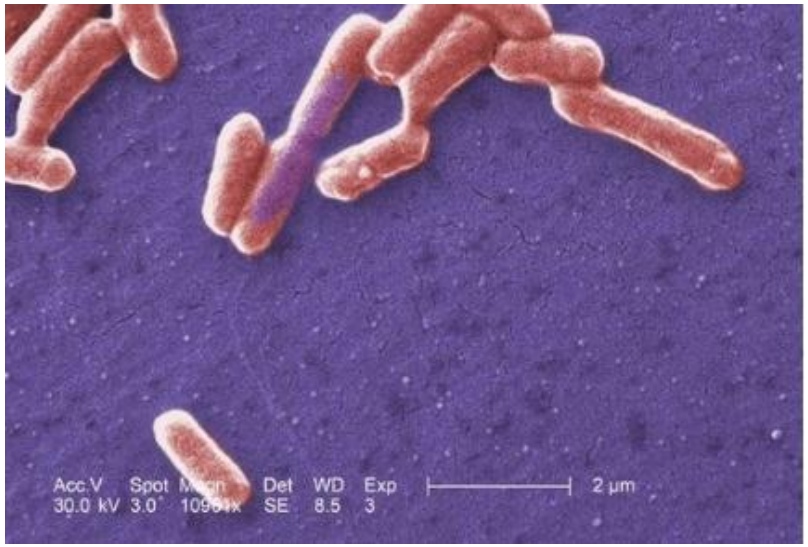
Science for Diplomats

Escherichia coli (E.coli)

- Weighs approximately 10^{-15} kilograms or

  1 picogram

- Can self-replicate every 15 minutes



Biological Facilities

- Freezer
  - Materials that you can't examine
- Production Line
  - Arrangement is Confidential Business Information

Draft Protocol – "Verification"

Article 6.

These visits shall:

- Increase confidence in the consistency of declarations with the activities of the facility and encouraging submission of complete and consistent declarations;
- Enhance transparency of facilities subject to the provisions of this section;

National Trial Visit

- Conducted at a government-owned facility
- Principal objectives of the trial visit:
  - To identify, explore, and evaluate negotiated access visit procedures to protect sensitive information
  - Attempt to access information providing openness and transparency relevant to the BWC
- Site was obligated to provide access, but to protect Confidential Business Information

National Trial Visit: Lessons Learned

- "Almost impossible to demonstrate that illicit BW activities are not, have not, and will not take place at the facility"
- Visiting team gleaned limited proprietary information
- Visiting team had heightened concerns about activities in areas where access was denied despite offered alternatives

Summary – “déjà vu all over again”

- Industry’s concerns remain valid.

From the U.S. Statement to the 24th Session of the Ad Hoc Group:

- “The arguments and justifications for the scope and nature of activities envisioned under the draft Protocol have used the CWC as the example of comparison. This is, unfortunately, seriously flawed.”
- “[T]he conceptual approach used…, although relevant in references to non-biological areas,… simply does not apply to biology.
- If we are to find an appropriate solution to the problem, we need to think ‘outside that box.’”