House Committee on Foreign Affairs  
Subcommittee on Europe, Eurasia, and Emerging Threats  

Hearing on Assessing the Bioweapons Threat:  
Russia and Beyond  

Prepared Statement of Amy E. Smithson, PhD  
Senior Fellow, James Martin Center for Nonproliferation Studies*  

May 7, 2014  

Some of the most vexing security problems facing the United States and the international community originate with disease. Public health services worldwide are already hard pressed to identify and respond to natural disease outbreaks. Enter the prospect of a state or terrorist group deliberately releasing disease, particularly communicable pathogens or ones that have been genetically-engineered to make them more lethal or contagious, and the problems for public health services multiply exponentially. For this reason, the Committee’s inquiry into biological proliferation concerns in Russia and Central Asia and into the lessons from past experience that should be factored into U.S. government preparations and policy for 2016 Review Conference of the Biological and Toxin Weapons Convention (BWC) is most welcome. I thank you for the opportunity to testify on these matters and hope that my research can shed light on the nature of the problem and constructive steps to prevent manmade biological epidemics.

My remarks are based on a trio of my biological nonproliferation projects. In a 1999 report called Toxic Archipelago, I described the proliferation threat posed by un- and underemployed former Soviet chemical and biological weapons scientists. Later, the Nuclear Threat Initiative funded my work to match former Soviet bioweaponeers with prospective research partners in the Western biopharmaceutical industry. My first-hand experience involves visits to over fifteen former Soviet bioweapons institutes and the conduct of a three-day crash course that taught over 120 weaponeers how to do business with their Western counterparts. In addition, I convened veteran U.S. biopharmaceutical industry scientists to solicit their views, concerns, and proposals about monitoring compliance with the BWC, and I interviewed the inspectors of the United Nations Special Commission (UNSCOM), who related what really transpired when they hunted down Iraq’s secret bioweapons program after the 1991 Gulf War. I summarize this important case history in this testimony but relate it in much more detail in Germ Gambits: The Bioweapons Dilemma, Iraq and Beyond (Stanford Univ. Press, 2011). Today, the Committee has the benefit not just of my thoughts, but of the rich experience and seasoned counsel of a great many of the world’s top experts in these matters.

Reducing Biological Weapons Threats in the Former Soviet Union  

While the Soviet Union paraded its nuclear weapons through Red Square for all to see, it cloaked its bioweapons program in secrecy and accelerated its work in germ weaponry after inaugurating the BWC in 1975 as a depository nation. The Soviet bioweapons program was roughly as large as its nuclear counterpart, with a work force of over sixty thousand scientists.

* Affiliation provided for identification purposes, only. The James Martin Center for Nonproliferation Studies does not take institutional positions on public policy issues.
and technicians, including ten thousand who developed and tested anti-crop and anti-livestock agents. According to several high-level defectors of this program, the Soviets went far past the classic agents like anthrax, pioneering the militarization of hemorrhagic fever viruses by successfully weaponizing Marburg, developing two different strains of plague to resist five known antibiotics apiece, and also altering strains of anthrax, tularemia, and glanders to make them resistant to known antibiotics and vaccines. Soviet bioweaponeers also attempted to create entirely novel virulent strains, including ones that produced toxins. Other Soviet scientists conducted research with bioregulators and neuro-modulating peptides, which are incapacitating agents that can affect individual behavior, for instance by stimulating insomnia and increasing aggressiveness. The capstone of this massive covert weapons program was stockpiles of hundreds of tons of anthrax and dozens of tons of plague and smallpox, mainly for use against U.S. and other Western non-battlefield targets.

In the years following the USSR’s collapse, U.S. Cooperative Threat Reduction (CTR) programmers in the State Department scrambled to reach these bioweaponeers with collaborative research grants to provide them with gainful employment that they desperately needed to support their families. Verbally, U.S. officials underscored for the weaponeers who received these “brain drain” prevention grants the condition that they must not share with their advanced knowledge of how to develop, test, produce, and disperse biowarfare agents or peddle weapons materials, particularly genetically-engineered pathogens. This condition appears to have been an important deterrent to misbehavior in the former bioweapons facilities, as the weaponeers began policing the behavior of their colleagues because they understood that funding would be severed for an entire facility if the U.S. government got a whiff that anyone from a facility was engaged in black marketeering or communication with suspected proliferators. The State Department’s scientist-to-scientist interactions also proved to be particularly helpful in acclimatizing the former Soviet bioweaponeers to the concept and practices of responsible science.

The Soviet bioweapons program involved dozens of research, development, and production sites. While the Defense Department’s CTR programming made some physical security upgrades at a handful of Russian institutes, Moscow was not receptive to proposals to consolidate their seed culture collections. Several other former Soviet states, however, welcomed CTR assistance, particularly Kazakhstan, where CTR aid dismantled the massive anthrax production plant at Stepnogorsk and decontaminated the test site at Vorozhdeniye Island. CTR assistance enabled security upgrades at 22 biological laboratories in Georgia and another 20 in Armenia, Kazakhstan, and Ukraine.

Institutionalization of best practices in safety and security and collaborative research with the former Soviet bioweaponeers helps them understand why their peers overseas eschew the militarization of diseases and can help reduce the possibility that weaponized seed cultures might leak from former Soviet bioweapons facilities. Given the potential devastation that could transpire should what is in the freezers of these institutes make its way into malevolent hands, policymakers should resist the temptation to consider this box as checked off the “to do” list. The U.S. government should spare no effort to continue to engage biological scientists and institute managers in Russia and Central Asia to reinforce the principles and practices of nonproliferation, to improve physical security at these sites, to train the scientists in best practices, and to enhance their disease surveillance capacity.
U.S. Preparation for the 2016 BWC Review Conference

The Committee has also asked what preparations the U.S. government should undertake in advance of the 2016 Review Conference for the BWC. This 1975 treaty lacks any on-site monitoring or inspection provisions because prevailing sentiment at that time, as conveyed by the 1968 British position, was that verification of a ban on biological weapons was “not possible.” International experts met in 1992-1993 to evaluate the ability of 21 procedures to monitor compliance with the BWC, but this preliminary assessment did not generate much political momentum leading into formal negotiations that began 1995 to create a legally binding inspection protocol for the BWC. These talks fell apart in 2001 after the U.S. government pronounced the draft procedures inadequate to detect cheaters yet likely to compromise trade secrets and national security. Thus, in the past few decades, the US government has repeated the statement that the BWC is “unverifiable.” On 7 December 2011, Secretary of State Hillary Clinton said that it was “not possible” to fashion a verification regime that could enhance confidence that states were in compliance with the BWC.

Counsel from Industry

The distinguished scientists who crafted the proposal that follows on prospects for BWC monitoring† have extensive experience in research, development, and production in large, multinational companies and smaller, niche pharmaceutical and biotechnology companies. To solicit their views on the verifiability of the BWC, I first asked these industry scientists to visualize the facilities they had worked in and to articulate what inspectors would need to do to catch illicit weapons activity at those sites. After they assembled their inspection methodology, I asked the industry experts to describe concerns they would have if their inspection strategy, tactics, and tools were applied at their respective facilities. The group identified concerns and then raised and agreed on ways to address those concerns while still satisfying the need of the inspectors to ascertain BWC compliance. In addition, I asked the industry experts to rate how effective their inspection methodology would be in practice and to compare how intrusive their inspection methodology was in comparison to the inspections of the Food and Drug Administration (FDA).

This group of biopharmaceutical industry insiders crafted a detailed monitoring strategy. To begin with, the industry experts recommended that the inspectors rely primarily on open source data, which is likely to be more plentiful, nuanced, and current than a country’s declaration. Legitimate pharmaceutical and biotechnology companies make considerable information available about their current and upcoming products, capabilities, and business objectives and practices to attract customers, investors, and media attention to increase sales. Once on site, the industry experts’ inspection methodology centers on evaluation of information that inspectors collect is inconsistent with a facility’s stated purpose.

After an overview briefing of the facility to be inspected, the industry experts proposed an extensive facility tour, with the host facility giving the inspectors critical documents, such as site maps and a piping-and-instrumentation diagram, that would allow them to zero in on unusual features or alterations that merited an explanation as well as any efforts by host officials to steer the inspectors away from important areas. The inspectors should have access to laboratories, the production floor, the product purification area, supply storerooms, the medical facility, the waste treatment area, and the animal facility, without compromising test protocols there. The industry experts recommended the standard inspection tools, namely observation, document reviews, and interviews. They were reticent to allow inspectors to photograph or video the inspection, instead proposing the “work-around” of providing additional information to address the inspectors’ inquiries. Of note, the industry experts proposed taking in-process samples if inspectors found indications of noncompliance. Samples would be stored in an onsite lock-box as host officials worked with the inspectors to resolve the compliance concerns. If those concerns persisted, the samples would be analyzed on site using a validated assay or in a certified third-party laboratory. Furthermore, the industry experts backed the notion of a challenge inspection on the heels of a routine inspection that unearthed compliance concerns that could not be resolved. Importantly, the industry experts’ BWC monitoring proposal could not be more contrary to the position of the PhRMA, the Pharmaceutical Manufacturers Association, which contends that just allowing inspectors on site would jeopardize trade secrets.

Next, the industry experts argued that skilled inspectors employing their monitoring strategy, tactics, and tools would be able to distinguish legitimate from cheating facilities while not compromising proprietary information. To wit, the industry experts believed the inspectors would really be able to get to the bottom of any possible inconsistencies with a facility’s stated purpose in certain physical areas of the facility, such as the waste treatment area, and by poring over documents. Substituting a fake set of documents to mask illicit military activity, the industry experts said, would be a monumental task. As Table 1 shows, the industry experts gave a majority of high inspection effectiveness ratings. Clearly, the industry experts believe that their verification proposal will work in practice. And, as it turns out, the UNSCOM inspectors

<table>
<thead>
<tr>
<th>Area of Inconsistency with a Site’s Stated Purpose</th>
<th>Expected Level of Effectiveness of Inspection Tools Used in Combination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of biosafety containment</td>
<td>High</td>
</tr>
<tr>
<td>Supplies</td>
<td>High</td>
</tr>
<tr>
<td>Equipment, materials of construction</td>
<td>Medium</td>
</tr>
<tr>
<td>Medical facilities</td>
<td>High</td>
</tr>
<tr>
<td>Plant facilities (e.g., cooling)</td>
<td>High</td>
</tr>
<tr>
<td>Waste handling, treatment systems</td>
<td>High with sample</td>
</tr>
<tr>
<td></td>
<td>Medium to low without sample</td>
</tr>
<tr>
<td>Procedures</td>
<td>Low</td>
</tr>
<tr>
<td>Management program</td>
<td>High to medium</td>
</tr>
<tr>
<td>Downstream processing</td>
<td>Very high</td>
</tr>
<tr>
<td>Degree of concern with product integrity/quality</td>
<td>High for human products</td>
</tr>
<tr>
<td></td>
<td>High to medium for animal products</td>
</tr>
</tbody>
</table>
proven the industry experts right. Much of what the industry experts proposed for monitoring the BWC bears a close resemblance to what UNSCOM inspectors did successfully when they unveiled the bioweapons program that Iraq spared no effort to hide from them.

When the industry experts assembled a trial inspection plan to test their proposal, they compared the intrusiveness of their BWC verification proposal to that of the inspections that the FDA conducts. The industry experts identified 16 similarities between these two inspection types, seven differences that they believed were unlikely to have any impact on the inspected facility, and another seven differences where their proposed BWC inspection practices would be less demanding than FDA inspections. Of note, the industry experts pegged just two differences where their proposed practices may be more demanding than FDA inspections. First, their BWC inspection team would be on site about five days. FDA teams often do not stay that long, but the industry group pointed out that the FDA sometimes shows up with no notice and stays as long as it deems necessary. Second, the FDA usually sends two or three inspectors. The industry experts believed that sites could accommodate the larger BWC inspection team that they propose, but the accompanying group of U.S. government escorts, who would also require a host facility escort for the duration of the inspection, might stress available manpower.

The industry experts drafted their and assessed their inspection protocol before I showed the group the details of the BWC protocol as it stood in 2001. One of the experts, Dr. George Pierce, summed up their reaction to the draft protocol as follows: “‘D’ is a good grade because that’s really the worst grade you can get. Sometimes an ‘F’ shows a little innovation.” So, the last thing to take note of is that these U.S. biopharmaceutical industry insiders argued for much more stringent inspection procedures than those contained in the draft BWC protocol.

Counsel from UNSCOM Inspectors

While the industry experts’ views remain in untested proposal form, the UNSCOM provides a treasure trove of biological field inspection experience. The ceasefire conditions of the 1991 Gulf War gave UNSCOM the role of overseeing the Iraq’s disarmament, pitting the inspectors against a country determine to retain its weapons of mass destruction and long-range missiles. When UNSCOM’s biological inspectors landed in Baghdad, Iraq had already established a strategy to conceal the bioweapons program, complete with tactics such as their requirement to be able to move sensitive materials or documents on fifteen minutes notice. Iraq’s bioweaponeers were also put on notice that they would be killed if they revealed anything to the inspectors. Next, this small group of inspectors knew full well that conventional wisdom held that inspections could not uncover a covert bioweapons program. Iraq’s first biological declaration to UNSCOM was null: Iraq claimed to have no biological facilities.

The final factor working against the UNSCOM inspectors was sketchy intelligence. The “signatures” of biological weapons programs are far less discernible than nuclear or chemical weapons programs. Even the telltale signs that do exist, such as the presence of high-level
biosafety containment, are not always reliable. Prior to the 1991 Gulf War, U.S intelligence did not identify Iraq’s main bioweapons production facility, Al Hakam, even though this site had a layout very similar to Iraq’s chemical weapons production site, Al Muthanna. In the late 1980s, Iraq powered up its germ weapons program with huge purchases of growth media, the nutrients needed for a biological seed culture to replicate itself. Before that, under the guise of legitimate research Iraqi scientists ordered the seed cultures for anthrax, botulinum toxin, and other agents from culture collections in the United States and France. U.S intelligence apparently did not notice these activities, but in the mid-1990s Israeli intelligence told UNSCOM that Iraq may have purchased a lot of growth media. In 2005, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction stated that the U.S intelligence community “substantially underestimated the scale and maturity of Iraq’s” biowarfare program before the 1991 Gulf War and that the U.S. intelligence assessment about the threat of Iraq’s rejuvenated biological and chemical weapons programs, notably its alleged mobile bioweapons production trailers, prior to the 2003 Gulf War was “simply wrong.”

So, to begin with the odds were stacked against UNSCOM’s biological inspectors, which makes what transpired during UNSCOM’s first two biological inspections all the more noteworthy. When UNSCOM biological inspectors first landed in Baghdad on August 2, 1991, the Iraqis switched from complete denial of a program to a hide-in-the-open strategy, declaring a program of military research that was applicable for defensive or offensive purposes. Over the next few days, the Iraqis said nothing that was consistent with biodefense work, but the inspectors saw hallmarks of an offensive weapons program. At Salmon Pak, the inspectors could see fresh bulldozer tracks from where Iraqis had bulldozed the aerosolization chamber building and the incinerator, two locations that would have provided the inspectors with incriminating evidence. In fact, the Iraqis left the bulldozer was sitting right there, making the “sanitization” of the site all the more evident. The inspectors tracked down an aerosolization chamber large enough to hold primates as test subjects, and they found large primate cages. The Iraqis blurted out that the head of their biological research program reported to Kamal Hussein, who was known to be a central figure in Iraq’s unconventional weapons programs. The Iraqis described their research to determine the LD$_{50}$ of pathogens, meaning the amount of agent they would need to disperse to kill fifty percent of the target population. Such research does not jibe with a defensive program, and the Iraqis were working with a strain of anthrax, the Vollum strain, that the United States had weaponized. Scientists typically keep copious records of their work, but Iraq’s bioweaponeers gave the inspectors a scant ten research papers. In short, although the inspectors found no biological weapons per se, they saw and heard plenty that pointed to an offensive bioweapons program.

The same was true of UNSCOM’s second inspection in mid-September 1991. The Iraqis had no real explanation for why the only biosafety level 3 facility in the country, Al Daura Foot and Mouth Disease Vaccine Facility, was operating at a fraction of its capacity even though the facility emerged unscathed from the war. Later, Iraq would admit that Saddam commandeered Al Daura to make warfare agent, and that the alterations the Iraqis made to the plant crippled it. Iraq first declared Al Hakam as a fermenter repair and storage facility, but as the inspectors entered Al Hakam the Iraqis switched stories, claiming the plant was making chicken feed, or single cell protein. UNSCOM inspectors quickly discovered that:
• Al Hakam’s layout was wholly inconsistent with a commercial plant;
• little economic justification existed for Al Hakam’s purported product;
• seed cultures at the site were inappropriate for a single cell protein plant but typical of a facility engaged in weapons work;
• Al Hakam was abnormally clean and did not appear to be producing much of anything;
• the plant’s supposed director did not know basic facts, such as the number of people he employed and Al Hakam’s production rates; and,
• the facility had oddly stringent security, not to mention dummy bunkers.

To top it off, trade journals or newspapers contained not a word about Al Hakam. A for-profit company would court the media to generate publicity to attract customers. In short, in its first two inspections, UNSCOM’s biological inspectors gathered significant evidence of a covert offensive bioweapons program despite Iraq’s efforts to hide the program, and they identified two purportedly commercial plants, Al Daura and Al Hakam, as likely to be involved in Iraq’s bioweapons work.

For approximately two and a half years, UNSCOM focused on other disarmament priorities in Iraq and did not conduct any dedicated biological inspections. When UNSCOM ramped up its biological inspections again in mid-1994, within several months the biological inspectors had collected sufficient evidence to cause Iraq’s cover stories to crumble and Iraq to admit on July 1, 1995 that it had produced bioweapon agents. The only intelligence tips the inspectors had to go on as they shredded Iraq’s cover stories were that Iraq apparently purchased large quantities of growth media, that Projects 85 and 324 were somehow linked to a possible bioweapons program, and that the Iraqis had tried to purchase high-containment ventilation equipment for buildings E and H, without any further specification as to the location of these projects or buildings.

To unmask the program, UNSCOM inspectors tripped up the Iraqis in interviews, gaining key insights into the architecture and activity of the Iraqi bioweapons program. UNSCOM sampled a sprayer on a second Al Hakam production line that the Iraqis claimed was making biopesticide. The sample contained ultra-small particles of *Bacillus thuringiensis*; particles under ten micros in size would be inoperable for a biopesticide but ideal for a bioweapon agent. UNSCOM gathered several hundred documents from Oxoid, Fluka, Niro Atomizer, Chemap, Olsa, Karl Kolb, and other suppliers to Iraq’s program. Analysis of these documents allowed the inspectors to reverse engineer Iraq’s bioweapons program, even determining that Al Hakam probably became operational in March 1988. UNSCOM’s ability to reverse engineer Iraq’s program was also aided when UNSCOM broke the codes on Iraq’s procurement documents, enabling them to determine Iraq’s plans for various items they purchased. The inspectors located 22 tons of growth media, but that left 17 tons missing. By that time, the inspectors knew Iraq had used the missing growth media to make bioweapon agents. As they pressed the Iraqis to explain where it went, the Iraqis slipped up and called Al Hakam Project 324. The Iraqis also turned over the engineering diagrams for Al Hakam, and there, clear as day, the research building and animal house were labelled buildings E and H. Contrary to popular thinking,
UNSCOM inspectors earned these and other revelations about Iraq’s bioweapons programs during routine inspections, not during no-notice or challenge inspections.

According to Iraqi Ministry of Health statistics, Iraq used barely a kilogram of growth media annually for hospital diagnostics, so the UNSCOM inspectors knew that Iraq’s assertion that hospitals had consumed the 17 tons of missing growth media was ludicrously false. The inspectors presented the Iraqis with an array of incriminating facts to paint them into a corner, forcing the Iraq’s mea culpa that Iraq made but destroyed its stocks of anthrax and botulinum toxin agent in 1990. Right away, the inspectors knew that Iraq was still not fully coming clean about its bioweapons program. After all, logic dictates that no state would go to all the trouble to make a super-secret weapon, only to demolish it before going to war. Moreover, the inspectors already had a handle on Iraq’s biological delivery systems, including bombs, missiles, and a sophisticated, finely crafted spinning dispersal device that a German company sold to Iraq. Therefore, in July 1995 UNSCOM Executive Director Rolf Ekeus briefed the United Nations Security Council that the inspectors contended that the Iraqi declaration was still incomplete, that Iraq had filled munitions with biowarfare agents. Despite Iraq’s extensive efforts to hide its bioweapons program, UNSCOM’s inspectors did what conventional wisdom says is impossible, they distinguished legitimate facilities from those involved in a weapons program and unearthed a covert bioweapons program.

**Concluding Thoughts**

When the U.S. government rightly charged that a 1979 outbreak of anthrax at Sverdlovsk was due a leak from a secret Soviet bioweapons facility, the United States could not provide the international community with evidence to back up these charges since the BWC has no inspection provisions. So, the USSR allayed the charges with the assertion that contaminated meat caused the outbreak. Even today, with everything that is known about the Soviet bioweapons program, Russian officials still occasionally revert to the contaminated meat explanation for the outbreak. Moreover, Russia’s 1992 voluntary declaration under the auspices of the BWC states that Soviet bioweaponeers failed to achieve anything militarily significant because of inadequate methodology, equipment, and materials and that therefore the USSR did not amass biological weapons.

Meanwhile, former top Soviet bioweaponeers have aired their suspicions that Russia continues to conduct offensive research and development. Russia still denies outsiders any access to key military biological facilities that were critical components of the Soviet germ weapons program, including the Center for Military-Technical Problems of Anti-Bacteriological Defense at Ekaterinburg; formerly Sverdlovsk; the Scientific Research Institute of Military Medicine in St. Petersburg; the Scientific Research Institute of Microbiology at Vyatka; and the Virology Center of the Scientific Research Institute of Microbiology at Sergeev-Posad. For these and other reasons, the 2013 U.S. arms control compliance report states that it remains “unclear if Russia has fulfilled its obligations under . . . . the BWC.”

Countless U.S. leaders have voiced concerns that terrorists might acquire biological weapons, but one must not forget that a state level bioweapons threat exists. Syria, which has recently used chemical weapons, has a bioweapons program, as does North Korea. Quite
frankly, because the BWC is devoid of inspection procedures, there is little assurance to be had that other countries might not be harboring bioweapons programs.

As noted, the intelligence community is seriously limited in its ability to find and characterize covert bioweapons programs, so there is a need to go back to the drawing board on data collection strategies, tactics, and tools that can be used to monitor biological facilities. The U.S. government appears to have done little to learn from the invaluable experience of the UNSCOM’s biological inspections, and this oversight must be corrected. With ordinary inspection tools—observation, document tracking, interviews—and old-fashioned gum-shoe detective work, UNSCOM’s inspectors collected considerable evidence of bioweapons programs, despite the façade of civilian activity. UNSCOM reported Iraq’s development, production, and weaponization of biowarfare agents to the Security Council, compelling Iraq to admit culpability. UNSCOM’s experience stands as a direct challenge to the U.S. policy that the BWC is “inherently unverifiable.”

Considering the counsel of top scientific experts from the U.S. biopharmaceutical industry and UNSCOM’s field experience, in preparation for the 2016 BWC Review Conference Congress should require the Executive Branch to employ these valuable resources to prepare a study evaluating the limitations and prospective contributions of intelligence and inspections to the standing need to detect and deter bioweapons proliferation. The study should address the utility of these tools in isolation of each other as well as the potential synergy between intelligence, increasingly powerful sampling and analysis capabilities, analysis of import/export data, and other on-site inspection tools. This study should include an assessment of how the global institutionalization of cross-cutting biosafety, biosecurity, and research oversight standards might benefit detection of covert bioweapons activity. As the U.S. industry experts observed, such standards would generate a voluminous data that can be perused to aid efforts to separate legitimate peaceful biological work from illicit biowarfare activities. To facilitate this study and inject additional on-site experience into the evaluation, the U.S. government should conduct a trial inspection based on the detailed plan laid out by the U.S. industry experts.

This proposed study could find that inspections can be expected to detect certain biowarfare activities reliably, such as the stockpiling of biological weapons and bulk agent production, but not necessarily to catch offensive research and development of biological weapons. Whatever the study’s conclusions, the analytical process entailed would be a springboard to identify alternatives to give U.S. policy makers more data of a more reliable qua about suspected bioweapons activities, which would in turn inform U.S. biodefense programs.