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Bridging Science and Security for Biological Research

Implementing the Revised Select Agents and Toxin Regulations Proceedings from the Meeting • 22-23 April 2013



BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH:
IMPLEMENTING THE REVISED SELECT AGENTS AND TOXINS REGULATIONS

Meeting Report
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Disclaimer

The concerns or suggestions outlined in this report reflect the discussions at the workshop and do not necessarily represent the views of the FBI WMD Directorate; AAAS Board of Directors, its Council, or membership; AAU Board of Directors or membership; or APLU Board of Directors or membership.

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About FBI/WMDD/BCU

The FBI's WMD Directorate (WMDD) was created after September 11, 2001 to provide a cohesive and coordinated approach to countering WMD threats and responding to incidents if they occur. Recognizing the unique and inherent challenges to preventing bioterrorism, the FBI/WMDD/Biological Countermeasures Unit (BCU) conducts extensive outreach to the life sciences community to proactively build mutually-beneficial relationships and broaden scientists' understanding of biosecurity concerns.

About AAAS

The American Association for the Advancement of Science (AAAS) is the world's largest general scientific society and publisher of the journal, *Science* (www.sciencemag.org). AAAS was founded in 1848, and serves 262 affiliated societies and academies of science, reaching 10 million individuals. *Science* has the largest paid circulation of any peer-reviewed general science journal in the world, with an estimated total readership of 1 million. The non-profit AAAS (www.aaas.org) is open to all and fulfills its mission to "advance science and serve society" through initiatives in science policy, international programs, science education, and more.

About AAU

The Association of American Universities (AAU) is a non-profit association of 60 U.S. and two Canadian pre-eminent public and private research universities. Founded in 1900, AAU focuses on national and institutional issues that are important to research-intensive universities, including funding for research, research and education policy, and graduate and undergraduate education.

About APLU

The Association of Public and Land-grant Universities (A•P•L•U) is a non-profit association of public research universities, land-grant institutions, and many state university systems and has member campuses in all 50 states and the U.S. territories. The nation's oldest higher education association, APLU is dedicated to advancing research, learning, and engagement. Current initiatives include efforts in math and science teacher preparation, international development, institutional accountability, online education, and more.

Table of Contents

Table of Contents

About the Project	4
<i>Bridging Science and Security for Biological Research</i>	4
FBI Biosecurity and Outreach Programs	4
Background	6
Select Agents and Toxins Regulations	8
The Meeting	10
Emerging Themes	12
Table: Participant Comments on Implementation of the Revised Select Agents and Toxins Regulations.....	15
Suggestions and Conclusions	20
Conclusion	22
Appendix 1: Meeting Agenda	24
Appendix 2: Meeting Participants	27

About the Project

The Federal Bureau of Investigation (FBI) Weapons of Mass Destruction Directorate (WMDD) has developed a robust biosecurity outreach and awareness program with the scientific community. To strengthen this relationship, the FBI WMD Directorate contracted with the American Association for the Advancement of Science (AAAS) to host a series of outreach and policy meetings with research, policy, and security stakeholders and summarize important lessons learned, challenges faced, and areas for improvement of local and national biosecurity initiatives.

Bridging Science and Security for Biological Research

This project is done in collaboration with the Association of American Universities (AAU) and Association of Public and Land-grant Universities (APLU), AAAS and the FBI WMD Directorate.

The first meeting, which was held in February 2012, provided opportunities for academic scientists and research administrators to build trust and enhance their relationship with the security community, with the mutual goal of jointly addressing the challenges of mitigating biosafety and biosecurity risks.

The second meeting, which was held in September 2012, provided the opportunity for scientists and research administrators to share best practices and lessons learned about the review and oversight of dual use life sciences research with each other and with the security and policy-making communities.

The third meeting, which was held in February 2013, focused on critical issues resulting from foreign scientists studying or working in the U.S., international collaboration, and U.S. scientists working in foreign countries.

The fourth meeting, which was held in April 2013, focused on the challenges faced during implementation of the revised Select Agents and Toxins Regulations and possible approaches for addressing those challenges.

FBI Biosecurity and Outreach Programs

The FBI contributes to the U.S. government's efforts to reduce the risk of bioterrorism by enforcing the federal statutes that prohibit development, production, or stockpiling of biological weapons. To accomplish these functions, the Biological Countermeasures Unit (BCU) of the FBI's WMD Directorate has developed biosecurity initiatives that focus on acquisition or exploitation of biological material, technology, and expertise to intentionally cause harm.

The BCU has established a successful biosecurity outreach program, the goal of which is to establish strong, sustainable relationships with officials and scientists from research

institutions to prevent and mitigate potential threats that they might encounter. The primary way in which the FBI engages with the scientific community is through their Academic Biosecurity Workshops. FBI WMD Coordinators conduct the workshops using a series of dialogues and exercises to bring relevant academic, health, first responder, law enforcement, and industry experts together to: 1) promote an understanding of their respective roles and responsibilities, capabilities, and resources; and 2) develop feasible, implementable threat mitigation strategies. The WMD Coordinators offer a point of contact at the local level and provide local support and security expertise. These efforts build on a shared goal of serving the public good.

The tangible benefits generated by these engagements are evident by the increasing number of requests for workshops by research institutions and interactions between institutions and their respective FBI WMD Coordinators. In addition, this model has garnered international attention; requests for assistance to implement similar academic workshops have come from both the law enforcement and academic communities of foreign nations.

Background

For centuries, infectious agents and toxins have been used as weapons against individuals and groups, since before the Siege of Caffa in the 14th century¹ to the letters containing ricin in 2013. Tribal groups, colonial settlers,² nation states, lone actors, and terrorist organizations have at one time or another considered developing or using pathogens and toxins as weapons. The use of biological weapons was prohibited in 1925 by the Protocol for the Prohibition of Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare (Geneva Protocol).³ However, the Geneva Protocol did not prevent countries from developing, producing, or stockpiling biological weapons, nor did it ban use altogether.⁴ Consequently, several countries developed offensive biological weapons programs incorporating and enhancing naturally-occurring pathogens.

Following several controversial incidents involving chemical weapons and an interagency review of key U.S. national security policies, President Nixon issued two National Security Decision Memoranda (NSDM) (NSDM 35 in 1969 and NSDM 44 in 1970), declaring his decision to destroy the entire U.S. stockpile of offensive biological weapons and to support only defensive research.⁵ Catalyzed by President Nixon's decisions and international efforts to eliminate biological weapons, twenty-two countries created and signed the Biological and Toxins Weapons Convention.⁶ This international treaty, which as of 2013 has 170 States Parties, prohibits the development and stockpiling of biological weapons while promoting research for peaceful purposes.⁷

In the midst of these efforts to prohibit the development and stockpiling of biological weapons, the World Health Organization achieved the global eradication of smallpox. This accomplishment led scientists, health officials, and clinicians to believe that infectious diseases could be controlled and eliminated. This belief changed in the late 20th century with the emergence of novel infectious diseases and unsuccessful eradication campaigns in the human population. Today, scientists and health experts better recognize the complexity of emerging and re-emerging infectious diseases, animal reservoirs of human pathogens, and the interconnection between human, animal, plant, and environmental health. The threat of biological terrorism has contributed to this complexity during the past 15 years.

¹ Wheelis, M. (2002) *Biological Warfare at the 1346 Siege of Caffa*. *Emerg Inf Dis*, 8(9), 971-975.

² http://cmgm.stanford.edu/biochem118/Papers/Simone_Brutlag/Amherst%20%26%20Smallpox.pdf

³ Protocol for the Prohibition of Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare. Available at: <http://www.state.gov/t/isn/4784.htm>. Accessed May 2, 2013.

⁴ Some security experts claim that the Geneva Protocol banned first use of biological weapons but left open the possibility that countries could use biological weapons in retaliation to an attack of equal or greater severity. Rissanen, J. (2003) The Biological Weapons Convention. Nuclear Threat Initiative. Available at <http://www.nti.org/analysis/articles/biological-weapons-convention/>. Accessed on May 2, 2013.

⁵ Tucker, J.B. and Mahan, E.R. (2009) *President Nixon's Decision to Renounce the U.S. Offensive Biological Weapons Program*. National Defense University (Washington, DC); the full memoranda are available on the Homeland Security Digital Library website (<https://www.hsdl.org/?collection/stratpol&id=pd&pid=rn>), Accessed on November 6, 2013.

⁶ Rissanen, J. (2003) The Biological Weapons Convention. Nuclear Threat Initiative. Available at <http://www.nti.org/analysis/articles/biological-weapons-convention/>. Accessed on May 2, 2013.

⁷ Biological and Toxins Weapons Convention. Available at: <http://disarmament.un.org/treaties/t/bwc>. Accessed on May 2, 2013.

By the mid-1990s, a confluence of events triggered a significant increase in U.S. concern about terrorist use of pathogens and toxins.

- The Japanese terrorist organization, Aum Shinrikyo, tried for a decade to acquire biological weapons – specifically Ebola virus, botulinum toxin, and *Bacillus anthracis*. In 1995, the group achieved success with the release of a chemical agent, sarin nerve gas, in the Tokyo subway system.⁸
- Hussein Kamel al-Majid, the son-in-law of Saddam Hussein, defected to Jordan with stories of undeclared stockpiles of biological weapons.⁹
- Larry Wayne Harris, a white supremacist in Ohio, ordered plague bacteria from a culture collection under false pretenses. At that time, no laws or regulations existed to minimize the possibility that dangerous pathogens could be obtained by individuals intending to do harm. Ultimately, Harris pled to a single count of wire fraud for falsifying information on his original request and received only probation.¹⁰ However, the U.S. government and a few civil society organizations began to understand the threat of bioterrorism. However, the overall effort was small compared to the actions taken after the events of 2001.

The September 11th attacks and the anthrax mailings in September and October of 2001 catalyzed significant investment (on the order of billions of U.S. dollars) in biodefense research: the development of new vaccines, drugs, and diagnostic tools as medical countermeasures against high priority pathogens and toxins; public health preparedness and response efforts; tracking of potential influenza pandemics; infectious disease surveillance; and more recently, global health security initiatives. The National Institute of Allergy and Infectious Diseases established Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases, consortia of academic and non-governmental research institutions, to conduct host-pathogen studies and develop medical countermeasures. The U.S. government built national and regional biocontainment laboratories to support this increase of research activities and public health identification and characterization efforts. The Department of Homeland Security established Centers of Excellence to support research on a different set of biodefense research efforts, including epidemic modeling, food safety and defense, and foreign animal diseases. Several U.S. government agencies – the Centers for Disease Control and Prevention (CDC), U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA), FBI, and Environmental Protection Agency – established laboratory response

⁸ Danzig R, Sageman M, Leighton T, Hough L, Yuki H, Kotani R, Hosford ZM. Aum Shinrikyo: Insights into How Terrorists Develop Biological and Chemical Weapons. (2011) Center for a New American Security. (Washington, DC). Available at www.cnas.org/files/documents/.../CNAS_AumShinrikyo_Danzig_0.pdf.

⁹ AP Archive. Jordan's King Hussain: Time for Change in Iraqi Leadership. (1995) Available at: <http://www.apnewsarchive.com/1995/Jordan-s-King-Hussein-Time-For-Change-In-Iraqi-Leadership/id-cd5a6306e3d7fd3db7f151d004bd1f30>. Accessed on November 7, 2013.

¹⁰ Carus, S. *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*. National Defense University. (Washington, DC, 2001); Stern, J.E. *Larry Wayne Harris (1998)*. In *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons* (Jonathan B. Tucker, ed.), pp. 227-245. (Cambridge, MA, 2001).

networks to coordinate disease detection and response to human, animal, and plant pathogens and toxins.¹¹

The White House issued several high-level strategies for prevention and response to natural or man-made biological threats. They included Homeland Security Presidential Directive (HSPD) 10/*Biodefense in the 21st Century*, HSPD 21/*Public Health and Medical Preparedness, National Strategy for Countering Biological Threats*, and the *National Biosurveillance Strategy*. At the same time, the U.S. government initiated several policy efforts to minimize the risks of misuse of research results¹² or theft of biological agents¹³.

Select Agents and Toxins Regulations

Select agents are pathogens and toxins that were assessed to have the potential to cause significant risk to public safety, national security, and economic interests. The Select Agents and Toxins Regulations were initially created in the mid-1990s in response to the Larry Wayne Harris incident to document the locations of certain pathogens and toxins (select agents) and individuals with access to those agents in an attempt to prevent illicit acquisition and use. The regulations have since undergone two significant changes - once after the 2001 anthrax letters and again in 2012. The principal agencies overseeing compliance with the Select Agents and Toxins Regulations are the CDC and the USDA Animal and Plant Health Inspection Service (APHIS).¹⁴ The FBI Criminal Justice Information Service (CJIS) conducts Security Risk Assessments (SRAs) of individuals seeking access to Biological Select Agents and Toxins.

In the wake of the 2001 events, the U.S. Congress passed the USA PATRIOT Act, which defined restricted persons and illegitimate uses of select agents. In 2002, Congress enhanced the Select Agents and Toxins Regulations by passing the Public Health Security and Bioterrorism Preparedness and Response Act. This bill expanded the list of highly regulated pathogens and toxins to include agricultural (animal and plant) pathogens; established the security risk assessment process to vet all individuals seeking access to select agents; and required registration of individuals and facilities possessing, using, and transferring select agents. These changes were made in response to the difficulties faced by the U.S. government in identifying the perpetrator and source location of the anthrax used in the 2001 anthrax letters. The SRA is a criminal database check to determine whether an individual seeking access to Select Agents and Toxins meet any of the statutory prohibitions (i.e., is a “restricted person”). Foreign scientists seeking to work with select agents also undergo a SRA. The final rule of the revised Select Agents and Toxins Regulations was released in 2005.

¹¹ The Department of Homeland Security coordinates efforts across the laboratory networks. See <https://www.icln.org/>.

¹² See the National Science Advisory for Biosecurity. Available at: http://oba.od.nih.gov/biosecurity/about_nsabb.html. Accessed on May 24, 2013; See also the Biological and Toxins Weapons Convention. Available at: [http://www.unog.ch/80256EE600585943/\(httpPages\)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument). Accessed on May 24, 2013.

¹³ See the Select Agent Program. Available at: <http://www.selectagents.gov/>. Accessed on May 24, 2013.

¹⁴ Based on a reorganization of USDA’s Veterinary Services and as of November 3, 2013, the roles and responsibilities of APHIS will be carried out by the Agriculture Select Agent Services (AgSAS).

In 2008, the U.S. Army expanded its personnel reliability program by issuing new regulations on biological surety¹⁵ for all individuals with access to select agents. Personnel reliability or surety programs are security measures used to identify and counter insider threats, i.e., personnel who might not be trustworthy or capable of performing a particular job function. Other organizations, such as Lawrence Livermore National Laboratory and the National Institutes of Health (NIH), have instituted personnel surety programs for individuals working with select agents; the NIH program applies to all personnel working in biosafety level 4 laboratories. Personnel reliability programs developed for biological laboratories strongly resemble those in place in nuclear weapons facilities; most personnel reliability programs involve psychological assessments and some include competency training for working safely in a laboratory to evaluate whether individuals should be granted access to select agents. In addition to these efforts, the National Science Advisory Board for Biosecurity was tasked to review existing personnel reliability programs and recommend measures to improve the vetting of individuals who seek to possess, use, and/or transfer select agents.

In 2008, the Congressionally-mandated Commission on the Prevention of WMD Proliferation and Terrorism released its report, *World at Risk*, in which the Commission described the likelihood of a biological attack by 2013 and measures needed to prevent such an attack.¹⁶ The recommendations enumerated in *World at Risk*, coupled with concerns about the insider threat and biosafety violations,¹⁷ prompted several Congressional and Executive Branch policy efforts to enhance the Select Agents and Toxins Regulations. Congress introduced two bills in 2009 to improve the Select Agent Program, neither of which became law. The Select Agent Program and Biosafety Improvement Act included measures for training, oversight, and voluntary reporting of accidental exposures to select agents and provisions involving the use of synthetic biology. The WMD Prevention and Preparedness Act included provisions on laboratory biosafety and biosecurity, the tiering of select agents into priority groups, vaccine and drug distribution, international biological engagement, and intelligence community reforms in workforce and capacity.

In parallel, the Executive Branch established an interagency working group through Executive Order 13486, *Strengthening Laboratory Biosecurity in the United States*, to review all existing laws, regulations, and policies related to the Select Agent Program, oversight and security of high-containment laboratories, and personnel security

¹⁵ AR50-1. Biological Surety Program, July 2008.

¹⁶ Commission on the Prevention of WMD Proliferation and Terrorism. *World at Risk*. (Vintage) 2008.

¹⁷ In 2007, a watchdog group informed the public that a non-select agent laboratory worker at Texas A&M University had contracted brucellosis, a disease caused by a select agent. The Select Agent Program and Department of Homeland Security (the project funding agency) took measures towards addressing oversight and compliance with the Select Agents and Toxins Regulations and funding agency requirements. While the university was implementing a series of changes to address the violations (reviewed in AAAS, AAU, APLU Competing Responsibilities), Congress requested an audit of select agent research in high-containment laboratories and established the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. The Trans Federal Task Force reviewed biosafety and physical security measures at the high containment laboratories in the U.S. They issued their report in 2009, recommending several measures, mechanisms for sharing best practices, and research needs to improve biosafety in high-containment laboratories. Available at <http://www.ars.usda.gov/is/br/bbotaskforce/biosafety-FINAL-REPORT-092009.pdf>. Accessed May 4, 2013.

measures.¹⁸ Following this review, the White House issued Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, which established the Federal Experts Security Advisory Panel (FESAP) to provide recommendations on tiering agents, removal of agents from or adding to the Select Agents and Toxins List, personnel reliability practices, physical and cyber security measures, and other relevant policy issues.¹⁹ The final rules of the Select Agents and Toxins Regulations, incorporating many of the FESAP recommendations, were released in 2012.

The newly revised regulations²⁰ designate 13 select agents as Tier 1 pathogens and toxins²¹ that require additional security protections, including development of an information security plan, reporting of incidents of theft, loss, or release to the FBI, compliance with minimum security standards for inventory verification of Select Agents and Toxins, and incorporation of intrusion detection systems. Security requirements for Tier 1 agents include the implementation of minimum standards for access control, back-up power, a personnel suitability assessment program, physical barriers, security training, and response time to a potential incident. Security measures were heightened further for smallpox and foot-and-mouth disease, including the breadth of restricted experiments for these agents. The revised regulations modified the Select Agents and Toxins List by removing five agents and adding three pathogens, including Severe Acute Respiratory Syndrome-associated coronavirus (SARS-CoV). In addition, the revised rules included provisions on recombinant and synthetic nucleic acids.

The Meeting

In April 2013, the American Association for the Advancement of Science (AAAS), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and the Federal Bureau of Investigation (FBI) convened a meeting of scientists, research administrators, and biosecurity experts to discuss the challenges of implementing the revised Select Agent and Toxins Regulations.

The *goals* of the meeting were:

- To identify challenges and best practices encountered in implementing the revised Select Agents and Toxins Regulations at research institutions with differently sized programs;
- To understand the effects of the revised Select Agents and Toxins Regulations on research and education at research institutions;
- To identify new challenges that have emerged with the implementation of the revised Select Agents and Toxins Regulations; and

¹⁸ <http://www.fas.org/irp/offdocs/eo/eo-13486.htm>

¹⁹ <http://www.gpo.gov/fdsys/pkg/FR-2010-07-08/pdf/2010-16864.pdf>

²⁰ HHS Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Final Rule; Fed Reg. 77(194), 5 Oct 2012; USDA Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Final Rule; Fed Reg. 77(194), 5 Oct 2012.

²¹ Ebola virus, *Francisella tularensis*, Marburg virus, Variola major virus, Variola minor virus, *Yersinia pestis*, Botulinum neurotoxin, Botulinum neurotoxin producing species of *Clostridium*, *Bacillus anthracis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, Food-and-Mouth Virus, and Rinderpest virus.

- To provide suggestions on how to address these challenges.

To encourage interaction and discussion, the meeting was held as not-for-attribution. We capture the major themes and policy-relevant issues that were presented at the meeting in the following sections: *Emerging Themes* and *Suggestions and Conclusions*. These sections are followed by two appendices that include the meeting agenda and list of participants.

Emerging Themes

Since its creation in 1997, the Select Agents and Toxins Regulations have undergone two significant revisions. Following the events of 2001, the U.S. Congress enacted legislation to make illegal the possession and use of pathogens and toxins for the intent of causing harm.²² The first major revision of the regulations went into force in 2005 and subsequently, any entity (including government, educational, non-profit, and for-profit research institutions and diagnostic laboratories) possessing select agents were required to comply with new rules. The first significant revision resulted in 82 pathogens and toxins – affecting human, animal, and plant health – being designated as restricted biological agents (the Select Agents and Toxins List). In addition, facilities in which select agents are housed and individuals who might have access to select agents (including laboratory workers, maintenance workers, veterinary and animal care staff, and cleaning staff) were required to undergo a criminal background check performed by the FBI-CJIS prior to gaining access to select agents. As with other regulations, research and diagnostic laboratories were subject to periodic inspections, oftentimes in an uncoordinated manner. (The CDC and APHIS established a system whereby they conducted joint inspections but other agencies, such as the Departments of Defense or Homeland Security, did not coordinate their inspections with the CDC and APHIS.)

In 2008 and prompted by *World at Risk*, a report from the Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, the federal government initiated a series of policy efforts that resulted in the second major revision of the Select Agents and Toxins Regulations. Public release of this report coincidentally followed the suicide of U.S. Army Medical Research Institute for Infectious Diseases researcher Bruce Ivins, the alleged perpetrator of the 2001 anthrax letters. The coincident release of *World at Risk* and Ivins' identity prompted significant discussion in the security policy community about personnel reliability for researchers with access to select agents and non-personnel security measures of select agent facilities. The result of four years of policy discussion and actions, the second revision categorized select agents into two lists – the highest priority threat agents (Tier 1) and the remaining list of select agents – and increased facility and personnel security, particularly for Tier I agents. The second revision was finalized in October 2012, giving research institutions and diagnostic laboratories six months to comply.

To better understand how research and diagnostic institutions have dealt with implementation of the 2012 revision of the Select Agents and Toxins Regulations, AAAS, AAU, APLU, and the FBI held a workshop with scientists and administrators from institutions possessing select agents for research and/or diagnostic purposes, and government officials. Meeting participants represented institutions with large or small select agent programs; public or private institutions; and research or diagnostic laboratories.

²² 18 U.S.C. 175a, b, (b), and c. This statute does not distinguish Select Agents and Toxins from other pathogens or toxins used to cause harm.

The section delineates the overall themes that emerged throughout the discussion and includes a list of representative comments on specific issues.

- Researchers, public health practitioners and institutional administrators face equally significant difficulties in ensuring compliance with the revised rules. In addition, lack of familiarity with personnel suitability requirements and shrinking resources have contributed to attrition in the staffs of select agent facilities. Some participants stated that such attrition would result in a significant reduction in the nation's capacity to detect, characterize, and respond to emerging natural or man-made biological events.
- The simultaneous efforts of implementing Select Agents and Toxins Regulations and strengthening the Regulations have posed significant challenges. Following the first major revision of the rules, limited financial and administrative resources were allocated for the maintenance of high-containment laboratories with select agents; lack of a formal mechanism for sharing best practices, lessons learned from accidents/accidental exposures, and corrective actions; and different inspection requirements and evaluations. These challenges are amplified as institutions seek to implement the 2012 revisions in today's economy.
- The Federal Select Agent Program faces the same significant challenges of limited financial and personnel resources as the regulated community work towards compliance to the more prescriptive requirements of the newly revised Select Agents and Toxins Regulations.
- Despite the origins of the Select Agents and Toxins Regulations to secure especially dangerous pathogens, the most recent revision of the Select Agents and Toxins Regulations has led to the perception that the regulations now heavily emphasize security measures over safety measures. This perception has resulted in scientists questioning the benefits of conducting select agent research and becoming concerned about the protection of privacy during personnel suitability assessments.
- Personnel suitability requirements – ensuring that those with access to select agents are trustworthy and capable – are extremely challenging to develop and implement. Participants discussed the added cost and burden of conducting criminal background checks at the local level and questioned how many individuals (i.e., information technology staff) must undergo these checks. The sharing of personal information with institutional officials or colleagues has raised serious concern among select agent researchers and some institutions have implemented complex processes to ensure protection of staff privacy. Few, if any, participants discussed issues of vulnerability, elicitation, trustworthiness, and other elements of a security suitability program.

- One significant change between the 2005 and 2012 revisions of the rules is the establishment of joint inspection groups wherein inspectors from CDC, APHIS and the Departments of Homeland Security, Defense, Energy, or other relevant agency inspect institutions at the same time. This step was taken to reduce the number of required inspections at each institution. However, institutions continue to face problems during inspection. Participants indicated that inspections should be tailored to the specific characteristics of the laboratories without compromising the regulatory standards. This would address current concern about failures being documented for items that do not apply to the institution being inspected (i.e., being cited for not receiving animal subjects training when no animals are used in the laboratory). Both of these issues detract from ensuring that institutions comply with the statutory requirements of the Select Agents and Toxins Regulations.
- Participants from smaller programs highlighted the importance of a strong supportive institutional environment in which to conduct select agent research under the newly revised regulations; in the absence of such an environment, administrative staff, researchers, and public health officials face serious challenges in implementing the regulations. Whether the institution primarily conducts research or diagnostic testing, the financial cost involved in establishing and maintaining a robust staff, administrative support, and safe and secure facilities is high. The financial burden mounts as institutions simultaneously face decreased funding from their state, increased regulatory requirements for a wide range of issues, and very little to no help from grants that support select agent research for personnel and physical security upgrades.

Because the implementation and compliance period for the 2012 revised Select Agents and Toxins Regulations recently ended, participants indicated that additional challenges might be encountered as their facilities, practices, record-keeping, and policies are inspected and their institutional personnel suitability programs are further developed and implemented.

Specific comments from meeting participants are listed in the table below. These comments are derived from participant experiences as they have begun to develop and implement practices and policies to address the increased security elements of the revised Select Agents and Toxins Regulations.

Participant Comments on Implementation of the Revised Select Agents and Toxins Regulations

Category	Revised Select Agents and Toxins Regulations	Participant Comments
Inventory/Access Control	The recently revised regulations have increased the inventory requirements for Tier 1 select agents.	<p>The administrative burden and information storage capacity is significantly greater for samples that are actively used in the laboratory compared to inventorying stored pathogens or toxins.</p> <p>Beyond knowing who has what pathogen, exact inventory rules are not informative or feasible, particularly for pathogens actively being experimented.</p> <p>Heightened inventory rules are an artificial means of going beyond the initial questions of who has what pathogen or toxin</p>
Natural Reservoirs	In addition to other naturally-occurring pathogens and toxins, Severe Acute Respiratory Syndrome-associated coronavirus (SARS-CoV) was added to the revised select agents list.	<p>Pandemics and epidemics caused by natural pathogens are the real and demonstrated public health issue compared to the threat of bioterrorism.</p> <p>Approximately five institutional administrators or researchers indicated they destroyed their SARS-CoV samples and a few administrators relayed they had accepted samples from researchers who left the field. Similar actions occurred when the Select Agent Regulations were first implemented (1995) and again when the regulations were revised for the first time (2001).</p>
Competitiveness	The revised Select Agents and Toxins Regulations enhance required security measures for 13 agents and toxins.	<p>The revised Select Agents and Toxins Regulations exacerbates the already burdensome research environment, potentially resulting in a competitive disadvantage of U.S. science.</p> <p>Scientists can work outside the U.S. and in countries where select agents are found naturally.</p>
Inspections	Inspections by relevant U.S. government agencies (including APHIS, the CDC, and DHS) are conducted jointly to minimize financial burden on the regulated community.	<p>Inspections have become too prescriptive, rely heavily on individual inspector interpretations of the regulations, and have moved away from performance-based measures that account for different institutional and local policies.</p> <p>Many of the requirements are statutory and several are regulatory; changing these requirements to meet the realities of facility design, institutional and local policies, and</p>

		<p>available workforce and laboratory capacity are difficult.</p> <p>Greater clarity and consistency is needed on the security standards to which they are held to meet the revised requirements.</p> <p>Non-federal employees are legally prohibited from participating on inspection teams but these experts would enhance the development of safety and security standards and practices that accounts for local and institutional policies, facility design, and available workforce.</p> <p>Increased training, communication and flexibility are needed to introduce consistency into the inspection process.</p> <p>The Select Agent Program may benefit from more staff and increased budgets to meet its federal statutory requirements.</p>
<p>Personnel Reliability and Suitability</p>	<p>Enhanced requirements for assessing the behavior, physical health, performance, and trustworthiness of scientists or relevant institutional staff seeking or having access to Tier 1 select agents.</p>	<p>Several research institutions established committees (or behavioral assessment teams) to vet employees and assess the validity of reported concerns about inappropriate or concerning behavior. However, participants expressed concern about potential conflicts of interest that some committee members might face when assessing new scientists because they might have a vested interest in seeing the research proceed and progress to further their own research efforts.</p> <p>An overwhelming majority of institutions represented at the meeting contacted their local FBI WMD Coordinator and/or campus police to help support the suitability assessments.</p> <p>In general, employee health assessments are funded through institutional overhead. All other checks, including background checks and psychological assessments, are currently supported through other means, including from campus police or external organizations that provide the service.</p> <p>Researchers are required to provide personal, health, and other information as part of the suitability assessment, which has caused concern among researchers about protection of their privacy. To address these concerns, some</p>

	<p>institutions have established new processes that separate different elements of the assessment. Some institutions have used previously existing behavioral threat assessment teams to assess the validity of reported concerns about inappropriate or concerning laboratory behavior. Some of these teams were initially created to alert the proper authorities of a possible campus violence situation.</p> <p>Information should be shared about appropriate approaches for handling situations in which employees have displayed negligent or otherwise concerning behavior.</p> <p>One institution now provides insider threat awareness training and information technology security training to their personnel. Local or federal law enforcement (i.e., campus police or the FBI WMD Coordinators) could provide training to scientists and institutional staff.</p> <p>One complication not originally anticipated is the role that unions play in suitability assessments.</p>
<p>Institutional Considerations</p>	<p>Institutions have begun asking whether select agent research supports the mission of the institution; whether the institution has the infrastructure needed to support select agent research; and whether select agent research will be a liability for the institution.²³</p> <p>Because facilities in which select agent research is conducted were built prior to institution of a tiered system, several institutions have chosen to maintain their select agent laboratories and associated administrative processes at Tier 1 required levels; consequently, all staff at these institutions are managed in the same way – at the Tier 1 level.</p> <p>Reassigning laboratory space to separate non-Tier 1 select agents from Tier 1 select agents would reduce the number of scientists having to undergo the enhanced Tier 1 security requirements.</p> <p>Many institutional administrators stated they</p>

²³ The primary liability concern is to the institution’s reputation, which can negatively affect its ability to receive funding, faculty members, students, and acceptance in the local community.

have significant trouble articulating the need for and the rationale behind the increased security requirements of the revised Select Agents and Toxins Regulations; the risks have not been adequately communicated to researchers and institutional administrators.

To increase the safety and security of select agent laboratories, several institutions have built or designated select agent facilities away from their broader research and/or educational community. Several participants raised concerns about isolating scientists from the rest of the research community. Isolation might cause a decrease in recruitment of early-career scientists into select agent research, effectively contributing to the eventual lack of the highly-skilled workforce needed to work safely with select agents and toxins.

Because of the increased time devoted to completing the administrative requirements of the revised rules, biosafety officials have less time to train their scientists on safety procedures and to practice these measures with scientists face-to-face.

Participants stated that the increased administrative requirements placed on researchers have resulted in a longer period of time for completion of projects, fewer publications, fewer career opportunities, and less professional growth.

Scientists and engineers from non-life science disciplines may be deterred by the stringent security regulations and choose not to participate in select agent research.

Although the newly revised Select Agents and Toxins Regulations do not require certain practices such as nondisclosure agreements, they are suggested in guidance provided by the Select Agent Program. Several research institutions have adopted these and other suggested measures because they are included in the guidance.

Different institutional policies and training requirements, and legal liability (in the case of an accident, misuse, or theft) concerns make

	<p>accepting visiting scientists challenging.</p> <p>Scientists have encountered delays in select agent approval if the pathogen for which they are seeking approval is due to be removed from the Select Agents and Toxins List.</p> <p>One of the side benefits of enhancing laboratory security is a heightened awareness of “dual use concerns.” (Dual use refers to the intentional use of beneficial biological knowledge, tools, materials, or technologies to cause harm.)</p>
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Suggestions and Conclusion

The 2012 revision of the Select Agents and Toxins Regulations requires research institutions and diagnostic laboratories to implement stringent physical security, cyber security, inventory, and personnel suitability and reliability measures for Tier 1 agents, pathogens and toxins of highest national security concern. Although this recent revision removed a few pathogens and toxins from the Select Agents and Toxins List, the majority of pathogens remained on the list and three viruses – SARS-CoV, Lujo and Chapare viruses – were added. The need for heightened security measures requires adequate communication to affected stakeholders, who face critical decisions about the long-term benefit of supporting select agent research in the current economic environment. Further, the implementation of new personnel suitability measures has eroded confidence between scientists and administrators at some research institutions.

The deadline to implement the requirements of the 2012 revision of the rules was April 3, 2013, just prior to this meeting. Meeting participants suggested approaches to alleviate the challenges faced during the first six months of implementation based on their experiences and lessons learned. **These suggestions, which are listed below, do not indicate source of funding, ease of implementation, or support for carrying out the action items.**

1. The U.S. government and research institutions should jointly develop a new, systematic approach for promoting, supporting, and overseeing select agent research. This approach could defray the costs from smaller research institutions, build regional and national networks in which scientists and administrators could share best practices and corrective actions, and facilitate collaborations to enhance research capacity and workforce development and reduce the overall number of institutions seeking access to select agents.
2. The U.S. government should provide a funding mechanism to support maintenance of existing facilities and infrastructure upgrades (both physical and personnel security efforts) to meet the new security requirements for Tier 1 Select Agents and Toxins. Some participants suggested that the U.S. government reconsider the current scientific infrastructure if biodefense and emerging infectious diseases are a significant concern. They suggested providing financial support for oversight of select agent research and promoting cooperation between science and health practitioners as approaches for maintaining the necessary research and human resource capacity to prevent and mitigate biological events of national and international concern
3. The U.S. government should develop a uniform template for field inspection reports that ensures comments and observations are recorded in the same order for each inspection. This template would be a significant enhancement beyond the checklist currently employed by focusing on inspector observations and facilitating the identification and review of previous findings associated with

- specific compliance requirements. This also might help reduce inconsistent and inappropriate inspections. In addition, a uniform template might help responsible officials and inspectors compare annual inspections more easily and identify repeated deficiencies over time. The U.S. government should seek input from the regulated community when developing the uniform field inspection report template.
4. The U.S. Select Agent Program should inspect safety and security requirements separately, but all should be inspected during the same site visit. The goal would be to ensure that both safety and security requirements are adequately evaluated without increasing the administrative burden of institutions.
 5. The U.S. Select Agent Program should prepare letters of interpretation or frequently asked questions for the most prevalent and/or concerning security findings encountered during inspections, particularly when inconsistent findings have arisen. Participants thought this would help reduce inconsistency among inspectors and inspections and improve local understanding of the standard to which they will be held.
 6. The U.S. government should require members of select agent inspection teams – regardless of their agency affiliation – to become familiar with research or diagnostic laboratories to better understand their standard operating procedures. Participants felt that this would help inspectors better understand how security/safety measures can be more effectively implemented.
 7. The Select Agent Program should identify and assess recurring infractions identified during inspections of different types of select agent entities. In addition, the Federal Select Agent Program should conduct blind evaluations of inspection reports. Participants thought the survey and evaluations might help prioritize findings and enhance consistency across inspections.
 8. The U.S. government should ensure the regulators and regulated community have a common understanding of the purpose of and differences between the new suitability requirements and existing FBI Security Risk Assessments.
 9. The U.S. government should periodically assess and update the guidance provided by the Select Agent Program to ensure the security measures included are appropriate and target actual security risks and to better assist institutions in complying with the regulations.
 10. The Select Agent Program should provide the regulated community with sufficient information to interpret the statutory security requirements and a broader array of acceptable security measures to increase the likelihood that institutions can achieve compliance with institutional, local, and federal policies.

11. The regulated community and U.S. government should consider the benefits and risks of re-integrating select agent laboratories with its parent organization (i.e., university or health department).
12. The U.S. Select Agent Program has provided useful guidance and should continue to provide similar support.
13. Institutions should provide insider threat awareness training and information technology security training to their personnel. Local or federal law enforcement (i.e., campus police or the FBI WMD Coordinators) could provide assistance in training to scientists and institutional staff.
14. Increased training, communication and flexibility amongst regulators and between institutions are needed to introduce consistency into the inspection process and uniformity in the implementation of the regulations.
15. Information should be shared amongst institutions about appropriate approaches for handling situations in which employees have displayed negligent or otherwise concerning behavior

Conclusion

The Select Agents and Toxins Regulations have undergone two significant changes during the past decade – the first in response to the 2001 terrorist events and the second following the publication of *World at Risk* and the findings from the federal investigation of the anthrax mailings. In parallel, the U.S. government has increased investments in the construction of new facilities to meet national diagnostic and research needs for the identification and mitigation of natural, accidental, and deliberate infectious disease threats. In addition, the U.S. government has funded numerous research projects to study emerging and advanced bioterrorism and public health risks.

The Select Agent Program has and will continue to provide guidance to research and diagnostic laboratories possessing select agents. However, the experiences of research institutions and public health laboratories in implementing the recently revised Select Agents and Toxins Regulations are a direct result of incongruous investments in research, diagnostic capabilities, and security regulations. The increased security requirements have led to added financial and administrative strains, and significant distrust between laboratory personnel and responsible officials, and concerns about privacy of scientists and other laboratory personnel. Consequently, regulated communities have either accepted and implemented (to the best of their abilities) the changes to the revised rules or abandoned research with restricted pathogens. To one meeting participant, the unique combination of decreased budgets, increased regulations, and increasing demands on the time of scientists and administrators suggests an inevitable shift in research agendas from biodefense to other research areas that are less burdensome.

The FBI, through its WMD Coordinators, will continue to engage and support Select Agent entities through the active participation of the FBI in the development of security plans at entities, training events, and exercises. This mutually beneficial engagement could facilitate rapid response and assessment when entities encounter security problems that impact their facilities, inventory, or personnel.

Appendix 1:

Meeting Agenda

BRIDGING SCIENCE AND SECURITY FOR BIOLOGICAL RESEARCH: IMPLEMENTING THE REVISED SELECT AGENTS AND TOXIN REGULATIONS

April 22-23, 2013
Washington, DC

Agenda

Day 1 (April 22, 2013)

Location: Tuscana West
1350 I Street, NW, Washington, DC 20005

6:30pm – 9:00pm **Reception and Dinner**

7:30pm – 8:30pm **Dinner Speaker**

The dinner session is designed to encourage active discussion among speakers about the meeting topic. The speaker will discuss the broader national context within which the revised Select Agents and Toxins Regulations exist.

Welcome: *Norman Neureiter, Ph.D.*, American Association for the Advancement of Science

Speakers: *Franca Jones, Ph.D.*, White House Office of Science and Technology Policy

Day 2 (April 23, 2013)

Location: AAU Conference Room
5th Floor, 1200 New York Avenue, NW, Washington, DC 20005

8:00am – 8:30am **Registration and Breakfast**

8:30am – 9:15am **Changes to the Select Agents and Toxins Regulations**

During this session, the speakers will discuss specific changes to the Select Agents and Toxins Regulations for human, agricultural, and overlap pathogens.

Moderator: *Kavita M. Berger, Ph.D.*, American Association for the Advancement of Science

Panelists: *Charles L. Divan, Ph.D.*, Animal and Plant Health Inspection Services

9:15am – 10:30am **Case Studies: Anthrax and SARS**

This session will focus on two examples in which speakers will describe the effects of the revised Select Agents and Toxins Regulations on research of a newly added pathogen (SARS) and a Tier I pathogen (anthrax).

Moderator: *Supervisory Special Agent Edward You*, Federal Bureau of Investigation

Panelist: *Rachel Roper, Ph.D.*, East Carolina University
Nancy Connell, Ph.D., University of Medicine and Dentistry of New Jersey

10:30am – 11:00am **Break**

11:00am – 12:30pm **Challenges Faced by Research Institutions with Existing Research Involving Tier 1 Select Agents**

This session is on challenges faced at the institutional level in implementing the revised Select Agents and Toxins Regulations. Speakers will focus their remarks on physical security, personnel reliability and suitability, education and training, communication, research conduct, and financial/administrative cost.

Moderator: *Carol Blum, Ph.D.* Council on Governmental Relations

Panelists: *C. Rick Lyons, M.D., Ph.D.*, Colorado State University
Joshua Goldberg, Esq., Goldberg Legal Services, LLC
Robert B. Harris, Ph.D., AIBioTech

12:30pm – 1:30pm **Lunch**

1:30pm – 2:30pm **Challenges Faced by Faculty and Staff in Complying with the Revised Rules**

This session is on challenges faced by scientists (faculty, student, or staff) as their laboratories and institutions implement the revised Select Agents and Toxins Regulations. Speakers will focus their remarks on physical security, personnel reliability and suitability, education and training, communication, research conduct, and opportunity costs.

Moderator: *Natasha Griffith, M.S.* University of California, Los Angeles

Panelists: *Julie A. Johnson, Ph.D., CBEP*, Kansas State University
Christina Egan, Ph.D., CBSP, Wadsworth Center and Association of Public Health Laboratories

2:30pm – 3:00pm **Break**

3:00pm – 5:00pm **Suggestions for Addressing Current Challenges**
During this session, facilitators will solicit additional comments and encourage sharing of information about best practices, needs, policy solutions, or help by the FBI WMD Coordinators to address challenges identified during implementation of the revised Select Agents and Toxins Regulations.

Facilitators: *Kavita M. Berger, Ph.D.*, American Association for the Advancement of Science
Kari McCarron, Association of Public and Land-grant Universities
Tobin Smith, Association of American Universities
Supervisory Special Agent Edward You, Federal Bureau of Investigation

5:00pm **Adjourn**

Appendix 2:

Meeting Participants

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