US Approach to the Control of Biological Materials

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Overview

- US Legislation going back more than 20 years

Biological Weapons Anti-Terrorism Act of 1989 (Public Law 101-298)

- Forms the implementing legislations for the Biological Weapons Convention (BWC)
- Made the possession, acquisition, development, production retention, or transfer of any biological agent, toxin or delivery system for use as a weapon punishable by a sentence that could include life in prison.
- The title made the connection between implementation of the Convention and the possibility that possession of a biological agent or toxin with the intent to use it as a weapon could be used as a weapon of terror.

Legal Definition—1989

- Biological Agent- any micro-organism, virus, or infectious substance, capable of causing—
  - death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
  - deterioration of food, water, equipment, supplies, or material of any kind; or
  - deleterious alteration of the environment.
- Toxin—any poisonous substance produced by a living organism; or any poisonous isomer, homolog or derivative of such a substance.

Antiterrorism and Effective Death Penalty Act, 1996

- Established that “the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety…”
- Amended the US Criminal Code, effectively making the definitions of biological agents broader.
- The Act added threats and conspiracy of biological weapons use to the existing crimes of use and attempted use.

Antiterrorism and Effective Death Penalty Act, 1996 cont.

- Ordered the Secretary of Health and Human Services to maintain a list of biological agents with the potential “to pose a severe threat to public health and safety.
- Lists the criteria for a threat to public health and safety which include: the effect on human health, the contagiousness of the agent, and the availability of relevant vaccines.
- Gives the Secretary of HHS the responsibility to regulate the transfer of biological agents.

The Uniting and Strengthening America by Providing Appropriate Tool s Required to Intercept and Obstruct Terrorism of October 2001 (the PATRIOT Act)

- Established a category of “restricted persons” to whom access to biological materials on the Select Agent List would be **denied**.
- Eight distinct categories.

PATRIOT Act Categories

1. Under indictment or convicted of a crime punishable by > 1 year in prison;
2. Fugitive from justice;
3. Unlawful user of a controlled substance;
4. An illegal or unlawful alien;
5. An alien from a country that supports terrorism;
6. Anyone committed to a mental institution;
7. Anyone dishonorably discharged from the military;
8. Anyone that a federal law enforcement or intelligence agency reasonably suspects of committing an act of terrorism that transcends national boundaries.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

- Passed shortly after 9/11 and the anthrax letters.
- Amended the 1996 Act in several important ways.
  - Required persons who possessed agents on the Select Agent List to register with the US Sec. HHS.
  - Specified registration information ;
  - Imposed obligations on those who registered.

National Select Agent Registry

- Under the Sec. HHS, oversees ***rules*** for possession of agents "that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products."
- Requires registration of facilities—government, universities, research and commercial entities.
- Final Rule issued March 2005—31 pages long.

Final Rule March 2005

- Nine virus groups,
- Five toxins,
- Two rickettsiae,
- One bacterium

Overlap select agents

- Five viruses
- Six toxins or toxin groups
- Nine bacteria

Nucleic acids that can produce infectious forms of the listed viruses etc.

Final Rule cont. defines “restricted experiments”

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally.
2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} <100ng/kg body weight.

Require prior approval from the HHS;

Provisions of Final Rule cont.

- Notification upon the theft, loss or release of any select agent;
- Secretary of HHS may inspect any site that conducts activities under this rule without notice;
- May inspect the premises of any individual or entity prior to granting a certificate of registration.

(Fink) Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology

"minimize threats from biological warfare and bioterrorism without hindering the progress of biotechnology."

First Report of the National Academy of Sciences to deal specifically with national security and the life sciences.

Recommendations of Fink Committee

1. Educating the Scientific Community;
2. Review of Plans for Experiments;
3. Review at the Publication Stage;
4. Creation of a National Science Advisory Board for Biodefense;
5. Additional elements for Protection Against Misuse;
6. A Role for the Life Sciences in Efforts to Prevent Bioterrorism and Biowarfare; and
7. Harmonized International Oversight.

Fink Committee
"Experiments of Concern"

1. Experiments that would demonstrate how to render a vaccine ineffective;
2. Experiments that would confer resistance to therapeutically useful antibiotics or antiviral agents;
3. Experiments that would enhance the virulence of a pathogen or render a nonpathogenic agent virulent;
4. Experiments that would increase the transmissibility of a pathogen;
5. Experiments that would alter the host range of a pathogen;
6. Experiments that would enable the evasion of diagnostic or detection tools; and
7. Experiments that would enable the weaponization of a biological agent or toxin.

Lemon Relman--Committee on Advances in Technology and the Prevention of their Application to Next Generation Bioterrorism and Biological Warfare

- Follow-up to Fink Committee
- Report: "Globalization, Biosecurity, and the Future of the Life Sciences" in 2006.

Lemon-Relman Charge:

1. Examine current scientific trends and the likely trajectory of future research activities in public health, life sciences, and biomedical and materials science that contain applications relevant to the development of “next generation” agents of biological origin five to ten years into the future.
2. Evaluate the potential for hostile uses of research advances in genetic engineering and biotechnology that will make biological agents more potent or damaging. Included in this evaluation will be the degree to which the integration of multiple advancing technologies over the next five to ten years could result in a synergistic effect.
3. Identify the current and potential future capabilities that could enable the ability of individuals, organizations, or countries to identify, acquire, master, and independently advance these technologies for both beneficial and hostile purposes.
4. Identify and recommend the knowledge and tools that will be needed by the national security, biomedical science, and public health communities to anticipate, prevent, recognize, mitigate, and respond to the destructive potential associated with advancing technologies.

Lemon-Relman Recommendations

1. Endorses and affirms policies and practices that, to the maximum extent possible, promote the free and open exchange of information in the life sciences.
2. Adopt a broader perspective on the threat spectrum.
3. Strengthen and enhance the scientific and technical expertise within and across the security communities
4. Adopt and promote a common culture of awareness and a shared sense of responsibility within the global community of life scientists.
5. Strengthen the public health infrastructure and existing response and recovery capabilities

National Science Advisory Board for Biosecurity (NSABB): 4 Reports

1. Addressing Biosecurity Concerns Related to the Synthesis of Select Agents, December 2006.
2. Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information, June 2007.
3. Strategic Plan for Outreach and Education on Dual Use Research Issues, December 2008.
4. Enhancing Personnel Reliability Among Individuals with Access to Select Agents, May 2009.
5. Addressing Biosecurity Concerns Related To Synthetic Biology, April 2010

National Strategy for Countering Biological Threats—December 2009

Threat of biological weapons from states has declined, the US is more concerned about bioterrorism.

1. Promote global health security;
2. Reinforce norms of safe and responsible conduct;
3. Obtain timely and accurate insight on current and emerging risks;
4. Take reasonable steps to reduce the potential for exploitation;
5. Expand our capability to prevent, attribute and apprehend;
6. Communicate effectively with all stakeholders; and
7. Transform the international dialogue on biological threats.

Conclusions

- Biosecurity will continue to be a combination of legislation, regulation and implementation of expert recommendations.
- US will not entertain proposals to strengthen the BWC through the 1995-2001 Ad Hoc Process.
- Proposals to the US government regarding actions for the Seventh Review Conference are likely to be seriously considered if they are connected to the language of the strategy statement.
- The new strategy may have significant room for new proposals and ideas.
- bioterrorism will continue to be a US focus.
- Political events could lead to change.