

# Globablizing Biosecurity

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# Mutually Reinforcing Strands

- Legally Binding
  - Access to dangerous pathogens
- Transparency
  - Biodefense programs
- Technology Transfer
  - Biosafety and biosecurity in developing countries
- Awareness
  - Dual use dilemma
- Responsible Conduct
  - Ethical codes and behavior

International Biological Weapons Convention

The diagram consists of three text elements arranged vertically on a blue background with a grid pattern. The top element is 'International Biological Weapons Convention'. The middle element is 'National Implementing Legislation'. The bottom element is 'Scientific and Health Community Codes of Conduct'. A white arrow on the left points downwards from the top to the bottom text. A white arrow on the right points upwards from the bottom to the top text.

National Implementing Legislation

Scientific and Health Community  
Codes of Conduct

# Biological and Toxin Weapons Convention

## ■ Article I

- Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
  - (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
  - (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.
- **Begins with development and not research**
- **Allows for biodefense for prophylactic and protective purposes**

# Filling the Gap

How to prevent terrorists from acquiring dangerous pathogens used in research and research knowledge that could be used for bioterrorism

# Material Control

## ■ CDC Laboratory Registration/ Select Agent Transfer Program

- These regulations placed shipping and handling requirements on laboratory facilities that transfer or receive select agents capable of causing substantial harm to human health. They were designed to ensure that select agents are not shipped to parties who are not equipped to handle them appropriately or who lack proper authorization for their requests.
- Required adherence to CDC biosafety manual (BMBL)
- Took effect April 1997

## ■ Export Control

- Australia Group

# USA Patriot Act—Personnel Security

- **Restrictions on who can possess select agents**
  - Restricts aliens from countries designated as supporting terrorism and those who could not possess a handgun from possessing select agents within the United States
  - Makes it an offense for a person to knowingly possess any biological agent, toxin or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by prophylactic, protective, bona fide research or other peaceful purpose.
  - In effect since October 26, 2001

# Biopreparedness Act

- Requires registration for possession of select agents
- Requires HHS and USDA regulations (Federal Register notice on December 9, 2002; regulations took effect February 7, 2003)
  - requires clearance by Department of Justice
  - tracks the acquisition, transfer and possession of certain biological agents and toxins
  - requires safeguards and security regulations to be followed
  - collects information for law enforcement;
  - establishes a process for alerting authorities about unauthorized attempts to acquire select agents



# Defining the List—Select Agents

## HHS NON-OVERLAP SELECT AGENTS AND TOXINS AGENTS AND TOXINS

- Crimean-Congo haemorrhagic fever virus
- *Coccidioides posadasii*
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- *Rickettsia prowazekii*
- *Rickettsia rickettsii*
- South American haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
- Tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis, Russian spring and summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever)
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

## HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- Botulinum neurotoxin producing species of *Clostridium*
- *Coccidioides immitis*
- *Coxiella burnetii*
- Eastern equine encephalitis virus
- Hendra virus
- *Francisella tularensis*
- Nipah Virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxin
- *Clostridium perfringens* epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxin

## USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AND TOXINS AGENTS AND TOXINS)

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- *Cowdria ruminantium* (Heartwater)
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Exotic)
- Menangle virus
- *Mycoplasma capricolum*/
- M.F38/*M. mycoides capri*
- *Mycoplasma mycoides mycoides*
- Newcastle disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (Exotic)

## LISTED PLANT PATHOGENS

- *Liberobacter africanus*
- *Liberobacter asiaticus*
- *Peronosclerospora philippinensis*
- *Phakopsora pachyrhizi*
- Plum Pox Potyvirus
- *Ralstonia solanacearum* race 3, biovar 2
- *Schlerophthora rayssiae* var *zeae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*
- *Xylella fastidiosa* (citrus variegated chlorosis strain)

# Germany

- **Act on the Reform of the Communicable Diseases Law (Communicable Diseases Law Reform Act) of 20 July 2000**
- Any person who wishes to import or export pathogens to and from the territory covered by this Act, store, supply or work with them there requires an authorization to do so from the competent authority.
- A person who works under the supervision of someone who either has an authorization, or requires no authorization shall require no authorization

# United Kingdom

## The Anti-terrorism, Crime and Security Act (ATCSA) 2001

- Strengthens legislation controlling weapons of mass destruction, and tightens controls on access to pathogens and toxins used in research laboratories in the United Kingdom.
  - premises (such as universities and research establishments) must notify the Government if they hold certain dangerous substances and sets up a register of premises holding specified pathogens and toxins.
  - confers powers on the police to inspect such premises and give directions as to their security.
  - requires managers of laboratories and other premises to furnish, on request, the police with details of people with access to any of the specified dangerous substances held there.
  - gives The Home Secretary power to direct that a named individual must not be allowed access to such disease strains or the premises in which they are held.
  - provides for extension to animal or plant pathogens and toxins

# World Health Organization

- “National standards should be developed that recognize and address the ongoing responsibility of countries and institutions to protect specimens, pathogens and toxins from misuse”
- “Global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment.”

# World Health Organization

- "Effective biosafety practices are the very foundation of laboratory biosecurity activities."
- "Assessment of the suitability of personnel, security-specific training and rigorous adherence to pathogen protection procedures are reasonable means of enhancing laboratory biosecurity."

# Technology Transfer

- To be effective in deterring bioterrorism, controls on dangerous pathogens must be global in reach, covering research and diagnostic laboratories
- Enhancing biosafety and biosecurity at all laboratories housing dangerous pathogens, especially those in the developing world, will require substantial financial and technical assistance.
- The needed technology transfer should be seen as crucial for enhancing global biosecurity and considered within the articles of the BWC



# Research Knowledge and the Dual Use Dilemma

- Advances in the life sciences, especially in molecular biology and informatics, and the potential for misuse of scientific research (the "dual-use" dilemma) raise the possibility that an act of terrorism could involve biological agents or that science could be misused for biowarfare.
- There is "*forbidden knowledge*."
- Some information should be classified or shared on a limited basis

# IAP STATEMENT ON BIOSECURITY

- In recent decades scientific research has created new and unexpected knowledge and technologies that offer unprecedented opportunities to improve human and animal health and environmental conditions. But some science and technology can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of "dual use" and the misuse of science and technology.



# The Export Control Act (2002)

- Includes control of information
  - “The Secretary of State may by order make provision for ... the imposition of transfer controls in relation to technology of any description”, providing the Government with an opportunity to stifle the flow of scientific knowledge and hamper international research collaboration.
  - “The Secretary of State shall not make a control order which has the effect of prohibiting or regulating the following activities—the effect of interfering with—the communication of information in the ordinary course of scientific research.

House of Commons Science and Technology Committee  
**The Scientific Response to Terrorism**  
November 6, 2003

- We recommend that the Science Minister raise the issue of the publication of research data with potential misuses with other EU Member States as a first step in drawing up an EU-wide code of conduct for scientific publication.
- Scientific communication must not become a casualty of the “war on terrorism”.

# Journal Editors and Authors Group

- The process of scientific publication, through which new findings are reviewed for quality and then presented to the rest of the scientific community and the public, is a vital element in our national life
- Questions have been asked by scientists themselves and by some political leaders about the possibility that new information published in research journals might give aid to those with malevolent ends.
- **Fundamental is a view, shared by nearly all, that there is information that, although we cannot now capture it with lists or definitions, presents enough risk of use by terrorists that it should not be published. How and by what processes it might be identified will continue to challenge us, because – as all present acknowledged -- it is also true that open publication brings benefits not only to public health but also in efforts to combat terrorism.**

# BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM: CONFRONTING THE DUAL USE DILEMMA

Report of the  
Committee on Research Standards and Practices to Prevent  
the Destructive Application of Biotechnology  
“Fink Committee”  
National Research Council  
OF THE NATIONAL ACADEMIES



# Defining the Sphere of Concern

- For the near term the Committee considered microbial pathogens and toxins as the primary threat
- The Committee identified seven classes of “experiments of concern” that illustrate the types of endeavors or discoveries that will require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail.
- These classes are process rather than organism based.

# Experiments of Concern

1. Would demonstrate how to render a vaccine ineffective.
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents
3. Would enhance the virulence of a pathogen or render a nonpathogen virulent
4. Would increase transmissibility of a pathogen
5. Would alter the host range of a pathogen.
6. Would enable the evasion of diagnostic/detection modalities
7. Would enable the weaponization of a biological agent or toxin

# US Government Biosecurity Initiative

- Establish the National Science Advisory Board for Biosecurity (NSABB) to advise and guide the government.
  - NSABB will provide advice and guidance regarding biological research that has the potential for misuse and could pose a biologic threat to public health or national security.
  - NSABB will advise HHS Secretary, NIH Director, heads of all Federal entities that conduct/support life sciences research.



# Summary:

## Possible Categories of Dual Use Research

### Research:

With agents that possess a high biological threat potential

That could increase the potential of an agent to cause harm

That could enhance susceptibility of host to harm

In enabling technologies and facilitating information

that may be misused to pose a biologic threat to public health and/or national security

Apply  
Criteria  
Developed  
from these  
Categories

Dual Use  
Research



# Conclusions

- Biosecurity must be global in reach
- Need to begin by better defining sphere of concern
- Need multi-pronged approach with both legally binding and ethical behavioral components
- Must develop culture of responsible conduct