

The Dual Use Dilemma

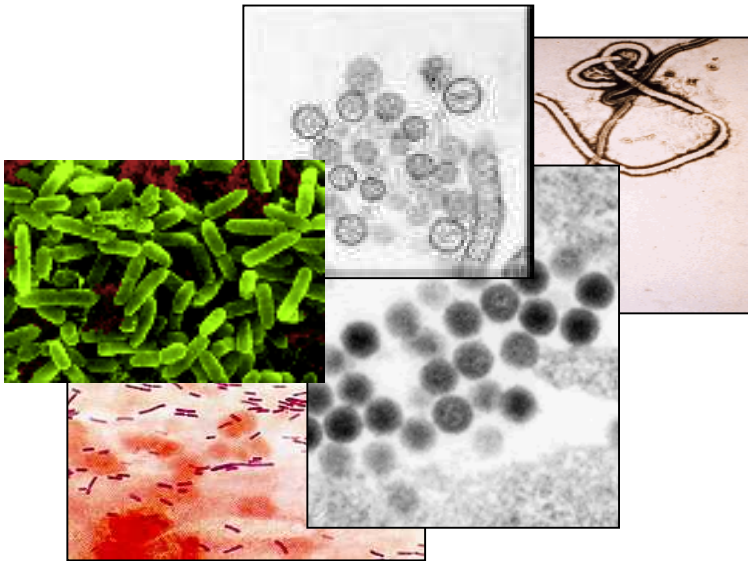
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www.biosecurity.sandia.gov



What is Dual-Use?

- **Traditionally, dual-use technology has both peaceful and military applications**
- **For bioscience,**
 - Materials, equipment, and expertise for legitimate bioscience that could be misused to create biological weapons or for bioterrorism
- **According to the Biological Weapons Convention, biological weapons are:**



“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.”



Historical Controls on Research

- **Historically, research is classified or not controlled**
 - Areas to be controlled identified prior to research and publication
 - “Born classified”
 - Classified areas predominately limited to research on weapons systems or nuclear technologies, NOT biology
 - If not classified, government did not typically place other controls on the information
- **Export controls limit the international export of advanced, domestically developed technologies and information**
 - Even if the technology is controlled, the underlying basic science is generally exempt and may be published in the open literature
- **National Security Decision Directive 189**
 - Sets as policy that fundamental research results are to be controlled only through classification
 - Issued in response to National Academies report concluding that openness in science leads to stronger long-term security
 - Issued in 1985, reaffirmed in Nov 2001 and Jan 2003



Current Controls on Dual-Use Bioscience

- **Export controls – National and Australia Group (AG)**
 - Use licensing measures to reduce likelihood that exports of certain biological agents and equipment do not contribute to the spread of BW
 - Control lists of biological agents and equipment
- **National biosecurity regulations and legislation to implement the Biological Weapons Convention. For example, in the US:**
 - Select agent regulations require facilities to implement a level of security for listed biological agents
 - USA PATRIOT Act:
 - Makes it a felony to possess a type or quantity of a biological agent that cannot be justified for prophylactic, protective, or peaceful purposes
 - Makes it a federal crime for convicted felons, illegal aliens or fugitives to possess or transport biological agents or toxins, in any quantity and for any reason



The “Dual Use” Dilemma

- **The various responses to the increased threat of infectious diseases will undoubtedly improve human and animal health and welfare**
 - But ... may also increase the global biological threat
- **Laboratories can be a cause of infectious disease outbreaks**
 - Laboratory-acquired infections
 - Laboratory-caused releases to the environment
 - Laboratories as the source of intentional theft and misuse
- **In addition, many of the tools, techniques, equipment, and materials used in laboratories to combat infectious diseases are “dual-use” – they can be used for good or harm**
 - Transparent surveillance networks that support early detection
 - Laboratory diagnostic methods that promote viral and bacterial isolation and amplification
 - Vaccine manufacturing facilities that amplify and store large quantities of pathogens, and that have the equipment and skills to produce large volumes of pathogens
 - Research techniques that require amplification and/or genetic modification of pathogens



World Reference Laboratory's internet-based surveillance system for FMD





Technical Requirements for Biological Weapons Use

- **Acquisition of high risk biological agents**
 - Bioscience facilities
 - Culture collections
 - Natural environment
 - De-novo synthesis / genetic modification of existing pathogen
- **Production of an adequate quantity of the agent in an adequate form**
 - Amplification of the agent and processing to prepare for dissemination
- **Dissemination of the viable agent through an effective delivery mechanism**
 - Most common routes of exposure for malicious dissemination to BW agents are inhalation, percutaneous, and ingestion
- **Dual-use materials, equipment, and expertise facilitate these technical requirements**





Dual-Use Materials – What Materials are of Concern?

- **Various control lists**
 - Select agent (SA) list
 - Australia group (AG) list
 - Category A, B, C list
- **Is everything on the list equally of concern from a BW / bioterrorism perspective?**
 - No:
 - Smallpox virus and Goat pox virus are both select agents
- **Do the lists include the same agents?**
 - Mostly but not completely:
 - Enterohaemorrhagic *Escherichia coli*, serotype O157 is on the AG list but not the SA list
- **Are their agents of concern not on any of those lists?**
 - Yes.
 - SARS, XDR-TB





Dual-Use Materials of Concern: Case Study

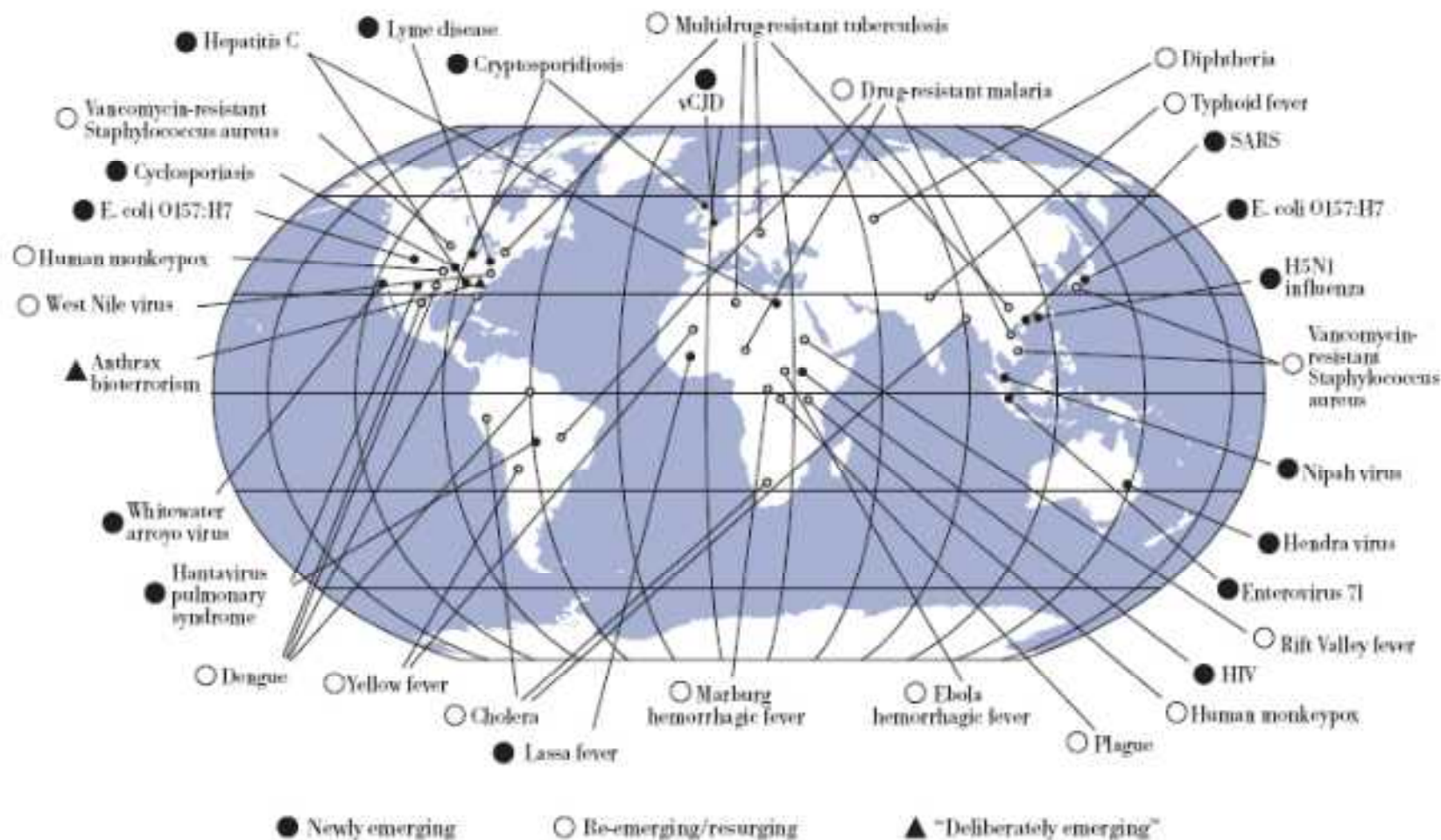
- **Maine Biological Labs**

- June 2001: MBL “is a fine example of a Maine-based company competing effectively in the global economy” Gov. King,
- July/August 2005: Fined \$500,000 and six employees convicted of various charges, including
 - **conspiracy, illegal exports, smuggling, false statements, aiding and abetting, and anti-boycott offenses**
- Offense:
 - **Exporting Newcastle disease virus vaccines to Syria without an export license on 3 separate occasions**
 - **Evidence was removed from the company to the garage of the company VP, the garage subsequently burned to the ground.**





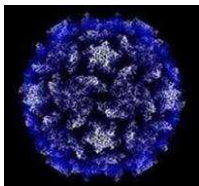
Wide Distribution of Biological Materials of Concern Challenges Efforts to Control Materials



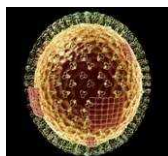


Rapidly Increasing Ability to Synthesize Biomaterials Presents Another Control Challenge

2002 Polio virus¹
7,741 bp



2005 1918 flu virus²
13,500 bp



2006 Marburg virus³
19,000 bp



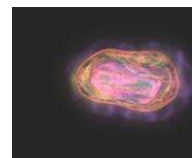
2008 SARS virus⁴
30,000 bp



2008 Mycoplasma⁵
582,970 bp



? Smallpox virus
185,000 bp



*“As DNA synthesis technology continues to advance at a rapid pace, it will soon become feasible to synthesize nearly any virus whose DNA sequence has been decoded—such as the smallpox virus”
-World at Risk, Dec 2008*

1: Science 2002, 9;297(5583):1016-8, 2: Science 2005 7;310(5745):77-80
3: J Virol 2006 80(2):1038-43, 4: PNAS 25 NOV 2008,
5: Science 2008 29;319(5867):1196-7



Dual-Use Equipment – What Equipment is of Concern?

- **Equipment controlled for export**
 - Listed equipment is large scale dual-use equipment with production and dissemination applications
 - Complete containment (BSL3 or BSL4) facilities
 - Fermenters (20 L or greater)
 - Centrifugal separators
 - Cross (tangential) flow filtration equipment
 - Freeze-drying equipment
 - Specific protective and containment equipment
 - Aerosol inhalation chambers
 - Spraying or fogging systems and components therefore
- **But, equipment not controlled within country**
- **Smaller (lab) scale dual-use equipment not controlled**





Distribution and Lifecycle of Equipment

Challenges Material Control Efforts

- **Global manufacturing and sale of equipment**

- Case study: Niro, Inc.



- Core technologies: spray drying, freeze drying, and fluid bed processing
 - Delivered 3 spray driers to Iraq allegedly for biopesticide production
 - Iraq Survey Group Report (30 September 2004) questioned sale when one spray dryer was found at al-Hakam
 - Later determined sale pre-dated any applicable export controls



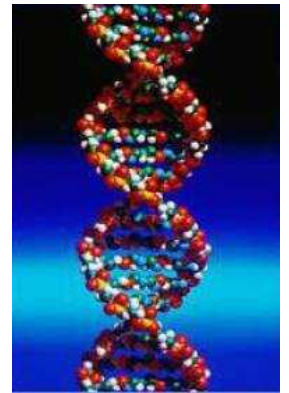
- **Decommissioning of equipment / second-hand market**

- Fermenters and other dual-use equipment can regularly be found for sale online
 - www.Lab-x.com
 - www.ebay.com



Dual-Use Expertise – What Information is of Concern?

- **National Academies Report on “Biotechnology in an Age of Terrorism” (Fink Report) defines 7 experiments of concern:**
- **Experiments that would**
 - Demonstrate how to render a vaccine ineffective
 - Confer resistance to therapeutically useful antibiotics or antiviral agents
 - Enhance the virulence of a pathogen or render a nonpathogen virulent
 - Increase transmissibility of a pathogen
 - Alter the host range of a pathogen
 - Enable the evasion of diagnostic/detection modalities
 - Enable the weaponization of a biological agent or toxin





Class Discussion of Recent Examples

- **PNAS publication of Botulinum toxin contamination of milk**
- **Science and Nature publications on 1918 influenza virus**



Key Conclusions and Opportunities

- **The biological threat has evolved in concert with**
 - Increasing emergence and reemergence of highly infectious disease
 - Advance of biotechnology globally
 - Rise of transnational, asymmetric terrorism
- **The materials, equipment, and expertise necessary for BW are**
- **Evolution of the threat has international community seeking new ways to balance legitimate bioscience with BW concerns**
 - Requires partnership between scientific and security communities





World At Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism

“...given the high level of know-how needed to use disease as a weapon to cause mass casualties, the United States should be less concerned that terrorists will become biologists and far more concerned that biologists will become terrorists.”

CONFRONTING 21ST CENTURY THREATS – www.barackobama.com

“We must not fixate on fighting the last war. The central concern is that as biological science and related technologies accelerate....bioweapons become ever more globally available”



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