

BIOSECURITY: UPGRADING THE WEB OF PREVENTION

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0. OUTLINE

- A. The Wider Context
 - Slides 1 - 3
- B. The Threat of Deliberate Disease
 - Slides 4 - 6
- C. The BTWC
 - Slides 7 - 12
- D. Policy Proposals
 - Slides 13 - 15
- E. Education
 - Slides 16 - 24

A 1. THE GENOMICS GATEWAY

- Launched in 2002 (www.genomics-gateway.net)
- Covers international regulation of biotechnology under six topics:
 - Health and Disease Control;
 - Environmental Protection;
 - Trade;
 - Protection against Misuse;
 - Drugs Control; and
 - Social and Ethical Impacts.

A 2. THE GENOMICS MONITOR

- Quarterly Report which:
 - Regularly updates information and provides analysis;
 - Highlights connections; and
 - Raises awareness of the scope and limitations of the current regulations.
- Issue No. 1 in November 2006
 - Provides an overview of objectives and methods.

A 3. GENOMICS MONITOR No. 5

- Analysis of 2007 FMD outbreak in the UK:
 - Asks whether outbreak would have happened if international standards had been followed;
 - Uses two main reports on outbreak;
 - Concludes that if international standards had been followed outbreak would not have occurred;
 - Notes confusion about meaning of ‘biosafety’ and ‘biosecurity’ in official report.

B 4. STATES AND SUB-STATES

- *US Adherence and Compliance with Arms Control... (2005)*
 - “...This Report addresses the activities of China, Cuba, Iran, Iraq, Libya, North Korea, Russia...and Syria....the United States has concerns regarding the activities of other countries...”
- *FBI Terrorism 2002 – 2005*
 - The use of WMD against civilian targets represents the most serious potential...terrorism threat...today and provides a glimpse into emerging terrorist scenarios of the 21st century...”

B 5. DUAL-USE RESEARCH

- NSABB
 - “...Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment or materials.”
- Netherlands Biosecurity Working Group
 - “...Interestingly, the NSABB adds the words ‘of concern’ to the term dual-use research. This implies that not all dual-use research is a cause for concern...”

B 6. IMPACT ON THE CWC

- IUPAC Report for Second Review Conference of the CWC in 2008
 - “...chemistry and biology are converging, thus reinforcing the importance of the overlap between the prohibitions and requirements of the CWC and the...BWC.”
 - “...significant advances in the understanding of complex life processes in a post-genomic era; and the ability to model life processes and develop synthetic and virtual replicas of living organisms...”

C 7. SIXTH REVIEW CONFERENCE OF THE BTWC

- Main Outcomes in 2006 *Final Declaration* (BWC/CONF.VI/6)
 - Article-by-Article Review of the Convention
 - Implementation Support Unit
 - Administrative Support;
 - CBMs.
 - Intersessional Programme 2007 – 2010
 - Promotion of Universalisation

C 8. IMPLEMENTATION REQUIREMENTS

- Sixth Review *WP 17* by Japan:
 - Effective legislative measures to ensure the prohibitions and preventions as required by the Convention;
 - Export controls; Security and oversight of pathogens; Enhancing preventive and response capabilities for natural or deliberate epidemics;
 - Education and enlightenment about biological weapon-related issues.

C 9. IN-DEPTH IMPLEMENTATION

- Sixth Review Conference *Final Declaration*:
Article IV
 - “14. The Conference urges the inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol. The Conference urges States Parties to promote the development of training and educational programmes for those...with the knowledge or capacity to modify such agents and toxins...to raise awareness of the risks, as well as the obligations of States Parties under the Convention.”

C 10. RESULTS: AUSTRALIA

- Experts Meeting 2005 *WP 29* by Australia:
 - “1. Amongst the Australian scientific community there is a low level of awareness of the risks of misuse of the biological sciences to assist in the development of biological or chemical weapons. Many scientists working in ‘dual-use’ areas simply do not consider that their work could inadvertently assist in a biological or chemical weapons programme...”

C 11. RESULTS: UK

- Bradford Briefing Paper *No. 16* (2005)
 - “There is little evidence from our seminars that participants:
 - a. regarded bioterrorism or bioweapons as a substantial threat;
 - b. considered that developments in life sciences research contributed to biothreats;
 - c. were aware of current debates and concerns about dual-use research; or
 - d. were familiar with the BTWC.”

C 12. RESULTS: *EU* SYNTHETIC BIOLOGISTS

- Bradford Science and Technology Report *No. 9* (2007)
 - “...Around a third of interviewees had heard of the Fink Committee and its report, and none was aware of the Lemon-Relman Committee and its call to broaden our understanding of the biosecurity threat...”
 - “...only a small number of the interviewees...were in a position to give an assessment of the various Committees, reports and recommendations addressed in the interview...”

D 13. *US* SYNTHETIC BIOLOGISTS

- *Synthetic Genomics: Options for Governance*
 - Gene Foundries
 - Require commercial firms to use approved software for screening orders.
 - Oligo Manufacturers
 - Require commercial firms to store information about customers and their orders.
 - DNA Synthesizers
 - Owners of DNA synthesizers must register their machines.
 - Users and Organisations
 - Incorporate education about risks and best practices as part of university curriculum.

D 14. INTERVENTION POINTS AND POLICY OPTIONS

- Funding
 - Modify application forms/procedures (Wellcome).
- Scientists
 - Educate better (US Synthetic Biologists).
- Project Proposal
 - Subject to oversight (Maryland Project).
- Project Activity
 - Under proper biosafety and biosecurity (WHO).
- Publication
 - Modify review system (*Science, Nature*).

D 15. POLICY ANALYSIS

- Baldwin and Cave (1999) *Understanding Regulation*
 - Command and Control
 - Force of law; Prone to capture;
 - Self-Regulation
 - High commitment to rules; Rules may be self-serving;
 - Incentives
 - Low-cost application; Poor response possible;

E 16. 2008 BTWC MEETINGS

- “(iii) National, regional and international measures to improve biosafety and biosecurity...
- (iv) Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and biotechnology research...”

E 17. BIO-EDUCATION MODULE WORKSHOP (11/2007)

- Rappert (2007) *Biotechnology, Security and the Search for Limits*
 - What should education entail by way of subject matter?
 - Dual-use research.
 - Who needs to be educated?
 - Both the participants and presenters.
 - What is the purpose of the education?
 - Discovering opinions, raising awareness.

E 18. EDUCATIONAL OBJECTIVES

- (i) To inform life scientists of the dangers of the hostile misuse of their benignly-intended work; and
- (ii) To enable life scientists to better take part in preventing the hostile misuse of their benignly-intended work.

E 19. MODULE ELEMENTS

- The problem of hostile misuse of the life sciences.
- The web of integrated policies that could help prevent misuse.
- The dual-use dilemma.
- The national regulatory system.
- Evaluation and assessment.
- Resources for students.

E 20. HOSTILE MISUSE

- Biological Warfare to 1945 (SIPRI).
- Biological Warfare from 1945 (Harvard).
- Future biological warfare/terrorism:
 - Science and Technology Background Papers for the BTWC/CWC Review Conferences;
 - *Biotechnology Research in an Age of Terrorism* (Fink, 2004);
 - *Globalisation, Biosecurity, and the Future of the Life Sciences* (Lemon-Relman, 2006).

E 21. THE WEB OF PREVENTION

- The development of the idea of a web of preventive policies centred on the international norm supported by a range of other policies.
- The 1925 Geneva Protocol, the BTWC and the CWC.
- The BTWC Intersessional Meetings:
 - National Implementation;
 - Codes of conduct and awareness raising.

E 22. THE DUAL-USE ISSUE

- Definitions
- Examples:
 - Mousepox; Polio virus; 1918 Spanish 'flu.
- Responses:
 - Oversight systems such as NSABB and Maryland (Controlling Dangerous Pathogens);
 - Proposals by synthetic biologists.
- Ethics

E 23. NATIONAL REGULATION

- Legislation to implement the BTWC and the CWC.
- Export controls.
- Biosafety and biosecurity.
- Enhancement of disease monitoring and response capabilities.
- Codes of conduct for life scientists

E 24. RESOURCES

- The Web of Prevention Website: A Practical Educational Initiative
 - Equivalent to the Genomics Gateway:
 - Take each regulatory intervention point;
 - At each point specify the regulatory options;
 - Update development of options regularly.
 - Equivalent to the Genomics Monitor:
 - Produce special analyses of important (and topical) issues each quarter.