

REGIONAL BIOSECURITY WORKSHOP

S.Africa May 28th- 30Th 2008

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Sponsors

- ▣ Co-sponsored by:
- ▣ Institute for Security Studies (ISS)
- ▣ Center for International and Security Studies (CISSM)-University of Maryland.

Biosafety ,Biosecurity & Biotechnology

- Basic Definitions:
- Biosafety:
- Measures taken to prevent exposure of lab workers or the public to pathogens or their toxins.
- Biosecurity :
- A broader concept that includes everything from controlling physical access to pathogens to ensuring that dual-use research is subject to effective oversight.
- Biotechnology:
- Different definitions on the web depending if you are pro or against Genetically Modified Organisms (GMOs).

Biotechnology

- ▣ Biotechnology: (Webster-dictionary)
- ▣ the manipulation (as through genetic engineering) of living organisms or their components to produce useful usually commercial products (as pest resistant crops, new bacterial strains, or novel pharmaceuticals); *also* : any of various applications of biological science used in such manipulation.

Focused of the Workshop

- ▣ Biosecurity aspect of Biotechnology focusing on the issue of “dual-use” biotechnology research.
- ▣ 2 primary goals:
 1. Help raise awareness about the “dual -use” issue.
 2. Obtain feedback on the proposals that have been developed for managing concerned areas of dual-use research.

Dual-Use biotechnology

- ▣ What is it?
- ▣ Basically the risk that the same techniques that have revolutionized the treatment of for e.g cancer and other terrible diseases could also be used to create new types of biological warfare agents

The Basic Principle of Protection

- ▣ Biotechnology must not be used to do deliberate harm under any circumstances for any reason.
- ▣ That basic principle is reasonably well established as a universal norm.
- ▣ Nonetheless must be substantially strengthened if it is to be the practical foundation for protection (*J. Steinbruner Univ. Maryland*).

Bio-Tech. Dangers some e.g

- ▣ In USA
- ❖ (Ref. *New Scientist* 10.29.03)
- Researcher (Buller) funded by US government as trials to counteract potential terrorist attack, develop a virulent mouse pox .
- The new virus kills all mice even if they have been given antiviral drugs as well as a vaccine that would normally protect them. .
- ❖ Department of Defense (DOD)-funded study, published in *Science* in July 2002, researchers from the State University of New York at Stony Brook created an infectious poliovirus from scratch by using genomic information available on the Internet and custom-made DNA material purchased through the mail.

Bio-Tech. Dangers some e.g. (continue)

▣ Soviet:

- ❖ Legionella bacteria were genetically engineered to produce myelin, resulting in an autoimmune disease with a mortality rate in animals of nearly 100 percent. (Soviet -late 1980s)
- ❖ genes from a bacterium that causes food poisoning, *Bacillus cereus*, were introduced into *Bacillus anthracis*, producing a more virulent strain of anthrax that even killed hamsters that had been vaccinated against the disease.

▣ Australian Universities:

- ❖ mousepox experiment, in which Australian researchers trying to develop a means of controlling the mouse population inserted a gene- created a pathogen that was lethal even to mice vaccinated against the disease.
- ▣ (ref. *“Controlling Dangerous Pathogens”*)

Emerging Threat

- ▣ 9/11-Anthrax
 - ❖ 5 people died and 17 were injured. An estimated 32,000 people were given antibiotics prophylactically, with some 10,300 of those being urged to continue treatment for 60 days.
 - ❖ What would have happened if a more sophisticated delivery system or an antibiotic-resistant strain of anthrax had been used instead? (*ref. Controlling Dangerous Pathogens-J. Steinbruner; E. Harris*)

Recommended Oversight-classing

- ▣ **Biological Research Security System (BRSS)**
 - ❖ International Oversight
 - Activities of Extreme Concern e.g work with small pox
 - ❖ National Oversight
 - Activities of Moderate Concern e.g work with Anthrax
 - ❖ Local Oversight
 - Activities of Potential Concern e.g by licensed researchers.
 - ❖ No Oversight
 - All other Research

7 Experiments/ Research of concern that would be considered for oversight

Those that would:

- Render a vaccine ineffective.
- Confer antibiotic or antiviral drug resistance.
- Enhance the virulence of a pathogen.
- Increase the transmissibility of a pathogen.
- Alter the host range of a pathogen.
- Evade diagnostic detection.
- Enable weaponization.

The System in Practice

- ▣ Any scientist wishing to carry out a research project subject to oversight under the BRSS would have to be licensed as would the facility where the proposed work would take place.
- ▣ In order to obtain a personnel license, the researcher would complete a new user questionnaire.
- ▣ Questionnaire:
- ▣ Inc. researcher's personal details, employment records; lab bio-security/facility, techniques to be employed, recombinant DNA work etc.

- ▣ A survey of journal articles published in the US from 2000 to mid-2005 indicated that some 310 US facilities and 2,574 US researchers would have been subject to the suggested BRSS oversight procedures had they been in effect .

E.g. of Oversight in UK

1998 Licensing requirement for laboratories and scientific establishments intending to hold or handle certain pathogens or nucleic acids capable of producing such pathogens.

2000 Requirement for a risk assessment prior to initiating work with a genetically modified organism and prior notification to UK health authorities of plans to carry out genetic modification work in any facility for the first time.

Suggestion for a global oversight system

- ▣ Biotechnology research clearly could, in the words of the National Academy of Sciences report, "cause disruption or harm, potentially on a catastrophic scale." This suggests the need for a more robust response, one that is comprehensive, mandatory and applies uniformly on a global scale.
- ▣ Under a global oversight system, participating governments would be required to establish review bodies to oversee and approve relevant research activities. No institution – whether academic, corporate or government – would be exempt from these oversight requirements. Participating countries would also be required to submit especially dangerous research activities to an international review body for approval.

A word of caution

- ▣ Over regulation could interfere with the freedom to address pertinent scientific questions and to be creative, which are the essence of the scientific process.
- ▣ However, exaggerated assessments of the biological weapons threat could lead to excessive spending on biodefense or bioterrorism research. Thus , diversion of funds from traditional areas of public health. (prof. leke University of Cameroon).

How about Africa?

Based on Feed Back from participants:

- ▣ Bio-Safety research in Africa mainly based on Cartagena Protocol –Agriculture .
- ▣ No serious medical research involving R-DNA on viruses being done apparently in African countries .

Africa Risk!

- ▣ African countries were more at risk because of their poor medical and Public Health infrastructures to contain potential viral or bio-terrorism threat .
- ▣ A concern among the African participants (inc. Seychelles) were the lack or limited bio-safety facilities even in Labs in the event of working/handling samples from a bio-terrorism threat. BSL3 (Bio-Safety Level 3) containment facilities or higher minimal/unsustained or not available.

Seychelles!

- ❑ No regulations in place at present e.g. at SLA /SBS relating to licensing of new Bio-laboratories.
- ❑ Under WHO requirements (Polio-Lab surveillance) Polio-Lab task force check biological labs on a yearly basis for samples and potential risk of virus storage
- ❑ Both Clinical and Public Health Labs have currently poor containment facilities-un prepared for handling new deadly viral threat re. SARS; H5N1 Flu; etc.
- ❑ Clinical lab has and is processing TB cultures.
- ❑ The Public Health Lab is and has been pressing for at least a BSL2 facility-matters still not finalized.

Concluding Statement from workshop included:

- ▣ In Africa, the primary concern is not the intentional misuse of science to cause harm, but rather, the risk to animal, plant and human health from natural disease outbreaks either originating on the continent or elsewhere.
- ▣ It is recognised that there is, nevertheless, a risk that human, plant or animal disease could be caused by an accidental or deliberate release of pathogens and products from laboratories.
- ▣ The public health systems of African countries have limited capacity to deal with large-scale disease outbreaks.
- ▣ There is an urgent need to improve the safety practices at laboratories and to develop policy and legislation in this regard

(continue)

- ▣ There is a need to educate and raise the awareness of scientists, from school to professional level, about the risks, rules and responsibilities associated with dual-use research.
- ▣ African governments and scientific associations need to become more involved in national, regional and international discussions and deliberations about biosecurity, and to start developing and implementing policies that promote safe, responsible science.
- ▣ The World Health Organisation (WHO) has an important leadership role to play in working with other partners to support countries to develop systems to prevent the misuse of the life sciences.

▣ *Thank you for your attention*