



**The Biosecurity Lexicon Project:  
Breaking down the Complexities  
of Biosecurity Science for Policymakers**



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# The Biosecurity Lexicon Project: Breaking down the Complexities of Biosecurity Science for Policymakers

By

Masamichi Minehata, Jaime Yassif,  
Karen Lu, and Caterina Dutto Fox

## Framing the Spectrum of Bio-risks and Bio-threats

### Wide Spectrum of Bio-risks and Bio-threats

Biotechnology, and more broadly the life sciences and related sciences, have been among the most rapidly growing areas of cutting-edge research worldwide in the 21st century. This has offered great social benefits including advances in public health, agriculture, and energy development around the world.



<i>Region</i>	<i>Annual Worth</i>	<i>Share</i>
North America	\$204 Billion	51%
Europe	\$102 Billion	25%
Japan	\$47 Billion	12%
Asia, Africa, Australia	\$32 Billion	8%
Latin America	\$17 Billion	4%

Note: National Research Council (2006) *Globalization, Biosecurity, and the Future of the Life Sciences*, Washington, D.C.: National Academies Press

Along with the benefits, however, this also leads to technological advances and globally diffused technology access that, in combination, could facilitate state and terrorist use of biological weapons.

### Threat Spectrum



Naturally occurring pandemic	Reemerging Infectious Diseases	Unintended Outcomes of Research	Laboratory Accidents	Lack of Awareness	Policy Choices	Crime & Counterfeit Drugs	Sabotage	BW Terrorism State
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Reference: Terrence Taylor, 2010

State-run bioweapon programs were developed throughout the World Wars, Cold War, and even following a period of the entry into force of the Biological and Toxin Weapons Convention (BTWC) in 1975.<sup>1</sup> The BTWC has not developed its formal organization or an effective verification mechanism, and has a lower level of membership to the Convention when compared to the Chemical Weapons Convention (CWC) and the Treaty on the Non-proliferation of Nuclear Weapons (NPT).<sup>2</sup> The Iraq Gulf War in 1991 and the following experience of the United Nations Special Commission in Iraq (UNSCOM) evoked concern about the proliferation of biological weapons to the states outside the Convention.<sup>3</sup> In the following year, Boris Yeltsin acknowledged State noncompliance with the Convention under the former Soviet Union.<sup>4</sup>

The anthrax attacks through the US postal system in the aftermath of Sept. 11, 2001 raised concerns about the malign application of science by non-state actors. Subsequently, alongside the publicly available research results on recombinant mousepox in the *Journal of Virology*,<sup>5</sup> a series of novel research results on the chemical synthesis of polio virus and the reconstruction of 1918 Spanish flu have been published in scientific journals. The implications of potential misuse of such research findings were highlighted by so-called Fink and Lemon-Relman reports from the National Research Council.<sup>6,7</sup>

The challenges to international security are more complex as bio-threats are not limited by the hostile use of biological agents. Even more significantly in terms of the number of human casualties and economic impact, there is a critical threat posed by the natural outbreak of infectious diseases such as SARS and Avian Influenza. Moreover, risks are also posed by accidental/unintentional exposure of pathogens to humans, animals and plants at increasing number of advanced biological laboratories<sup>8</sup> dealing with higher level of pathogens, including biorisks, threat and hazard at the laboratory level.

**Biorisk** is “the probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.”

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<sup>1</sup> Wheelis, M., Rozsa, L., and Dando, M.R. (Eds.) (2006) *Deadly cultures: biological weapons since 1945*. Cambridge, Mass.; London: Harvard University Press

<sup>2</sup> In 2007, compared with the CWC (182 ratifications) and the NPT (189), the BWC has achieved much less adherence with just 155.

<sup>3</sup> Graham S. Pearson. (2000) *The UNSCOM Saga: Chemical and Biological Weapons Non-Proliferation* London: Palgrave Macmillan.

<sup>4</sup> Federation of American Scientists “Russia Commits to End Biological Weapons Program,” *Biological Weapons Convention News*, September 1992, <<http://www.fas.org/nuke/control/bwc/news/920914-242819.htm>>.

<sup>5</sup> R. J. Jackson, A. J. Ramsay, C. D. Christensen, S. Beaton, D. F. Hall, and I. A. Ramshoaw, (2001) “Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox,” *Journal of Virology*, vol. 75, no. 3, pp. 1205-1210.

<sup>6</sup> National Research Council (2004) *Biotechnology Research in an Age of Terrorism*, Washington, D.C.: National Academies Press.

<sup>7</sup> National Research Council (2006) *Globalization, Biosecurity, and the Future of the Life Sciences*, Washington, D.C.: National Academies Press.

<sup>8</sup> WHO. (2006) *Biorisk Management: Laboratory Biosecurity Guidance*, WHO\_CDS\_EPR\_2006\_6, Geneva: WHO.



**Threat** is “the likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.” and

**Hazard** is “a danger or source of danger; the potential to cause harm.”<sup>9</sup>

**The Life Sciences** “include any field of science that is leading to or has the potential to lead to an enhanced understanding of living organisms, especially human life. These sciences include, for example, branches of mathematics and computational science, as these are now being applied in efforts to effectively model a wide variety of biological systems, or materials science, as it is applied to the manipulation of biological systems.”<sup>10</sup>

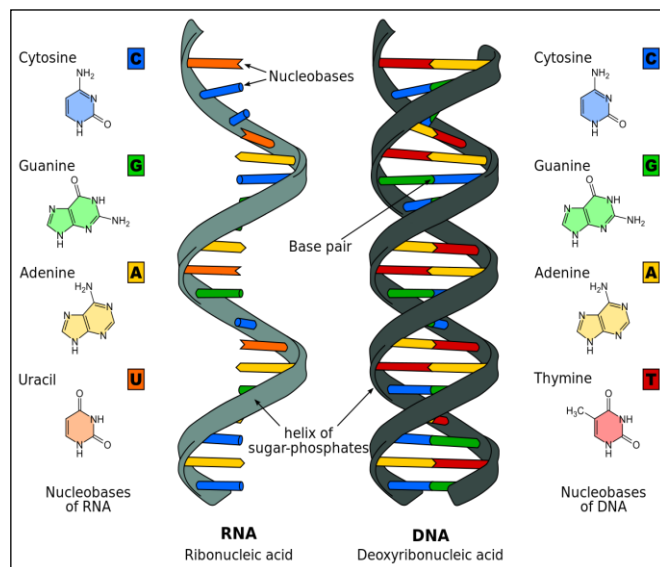
**Associated Technology of the life sciences** “refers to the development and application of tools, machines, materials, and processes based on knowledge derived within or applied to the life sciences: genetic engineering, synthetic biology, aerosol technology, combinatorial chemistry, and nanotechnology are just a few of these technologies.”<sup>11</sup>

## Life Sciences Technical Terms

This section explains technical terms relevant to the life sciences and biosecurity:

- **DNA** (deoxyribonucleic acid) is the blueprint for life; it is an information-encoding molecule providing instructions for the structure and function of cells, viruses, and more complex organisms. Each DNA molecule is made of two strands, and each strand is comprised of a long chain of four types of building blocks called nucleotides: Adenine (A), Thymine (T), Guanine (G) and Cytosine (C). The sequence of nucleotides stores the information encoded in DNA. The two DNA strands bind each other in a sequence specific manner, forming a double helix, in which the nucleotides form A-T and G-C base pairs – like rungs on a ladder.

- **RNA** (ribonucleic acid), another type of information encoding molecule, is comprised of similar nucleotides as DNA, but it is single-stranded.



**Figure 1. DNA and RNA structure** (Wikimedia Commons)

<sup>9</sup> Ibid.

<sup>10</sup> National Research Council (2006) *Globalization, Biosecurity, and the Future of the Life Sciences*, Washington, D.C.: National Academies Press. P. 27

<sup>11</sup> Ibid.

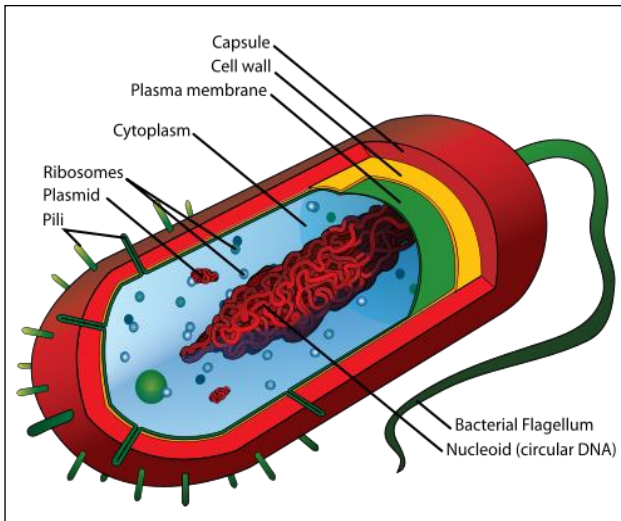
- A **genome** is the complete set of genetic material that encodes the instructions for all materials produced by the cell and how to control cell behavior under different conditions. Most genomes are comprised of DNA, but some viral genomes are made of RNA.

The set of genetic instructions in bacteria, the bacterial genome, usually ranges in size from millions to tens of millions of base pairs. For example, the anthrax genome has 5 million base pairs. Viral genomes are considerably smaller than those of bacteria – ranging in size from thousands to millions of bases. The smallpox virus, for example, is 200,000 base pairs long. The human genome is approximately 3.2 billion base pairs long.

Bacteria and viruses make up the majority of pathogens likely to be used in an attack or to be the source of a natural outbreak.

- **Bacteria** are living single-celled organisms. A defining feature of bacteria is that, in contrast to the cells found in animals and humans, bacterial DNA is not segregated into a separate compartment, called the nucleus.
- **Viruses**, unlike bacteria, are not cells. They are comprised of genetic material tightly packed into a protein and lipid shell. This genetic material can be either DNA or RNA. Viruses invade living cells and take over the cell's machinery by inducing the cell to express the viral genome and to make copies of the virus so that it can reproduce.

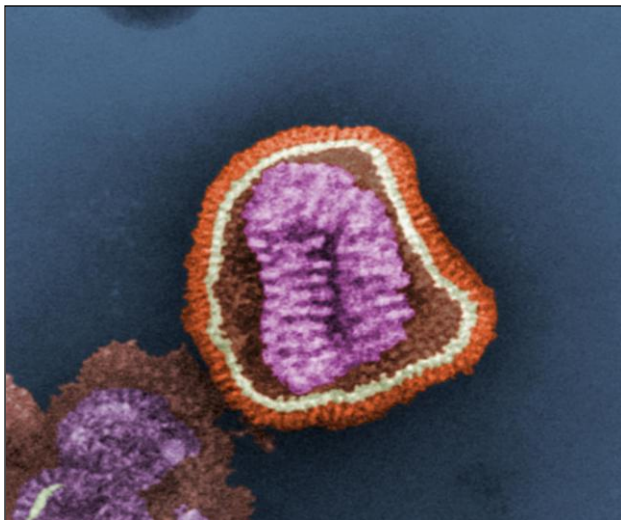
Thousands of laboratories worldwide study and manipulate bacteria and viruses – often referred to as microbes – for basic and applied research.



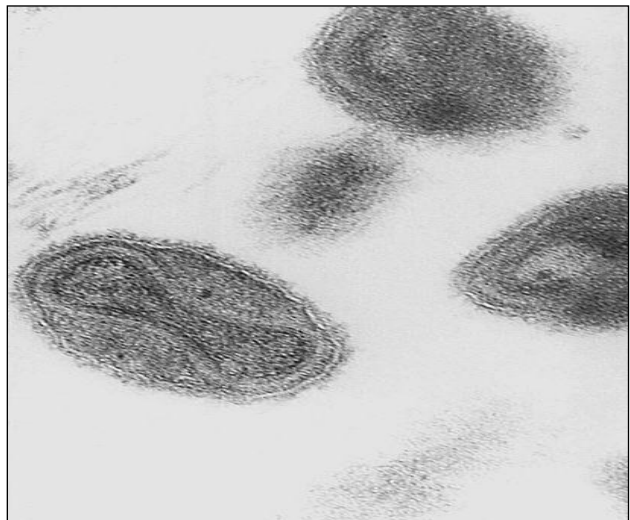
**Figure 2. Schematic Diagram of a Bacterium.** The red material in the cell center represents the bacterial DNA. (Mariana Ruiz Villarreal)



**Figure 3. Anthrax bacteria** (Centers for U.S. Disease Control Public Health Image Library)



**Figure 4. Influenza Virus.** The viral genome, which in this case is single-stranded RNA, is false colored pink in this image. (US Centers for Disease Control Public Health Image Library. Photo Credit: Frederick Murphy.)



**Figure 5. Smallpox Virus.** The “dumbbell-shaped” structure inside the smallpox virion contains the viral DNA. (US Centers for Disease Control Public Health Image Library. Photo Credit: Fred Murphy and Sylvia Whitfield.)

- **Select Agents** are a group of pathogens and toxins, which have been identified by the U.S. Departments of Health and Human Services and Agriculture as posing severe health and safety threats to human and animal populations. Dozens of biological agents are included on the Select Agent list. The US Centers for Disease Control regulate the laboratories that work with and store these agents, and these laboratories must adhere to safety and security requirements.<sup>12</sup>
- **Toxins** are poisonous compounds produced by cells or living organisms. These compounds are typically comprised of small organic molecules or proteins, and the most potent toxins, such as botulinum toxin and ricin, are lethal in very small quantities. Both ricin and botulinum toxin have been produced in the past for weapons use, however the production and stockpiling of toxins for military purposes is banned by the Biological and Toxin Weapons Convention (BTWC).<sup>13</sup>
- **Biosafety Level 3 (BSL-3) and BSL-4 laboratories** are high containment laboratories designed to provide a safe environment for researchers to work with potentially lethal pathogens. The safety requirements at these facilities are part of a continuum of four safety levels for biological research, BSL-1 through BSL-4, in which level 4 is designated for experiments with the most dangerous materials.

BSL-3 sites are used for research on potentially lethal pathogens that are capable of airborne transmission. These labs must include specialized safety features, such as sealed windows and custom ventilation systems. BSL-4 laboratories are designed for research on lethal pathogens, for which there is no vaccine or treatment. In addition to BSL-3 safety features, BSL-4 labs include additional precautions, such as ventilated full-body suits and glove boxes. In addition to these engineering controls, safety measures at BSL-3 and BSL-4 labs include immunizations, training and procedures, and personal protective equipment – such as gloves and masks.

There are dozens of BSL-4 and thousands of BSL-3 laboratories worldwide, and the number of these high containment facilities is rapidly growing. This expansion has resulted from efforts to manage the risks posed by emerging infectious diseases and the growing economic benefits of biomedical research.<sup>14</sup>

- **DNA synthesis** is the process by which DNA strands are formed synthetically in a test-tube. Nucleotides (A, T, G and C), the building blocks of DNA, are chemically linked together to form long chains of DNA according to a defined sequence and without a natural template. DNA synthesis is used to produce DNA segments that range in size from short pieces to long segments that comprise several genes, and

<sup>12</sup> National Select Agent Registry < <http://www.selectagents.gov/index.html> >.

<sup>13</sup> “What Are Biological and Toxin Weapons?” United Nations Geneva. <<http://www.unog.ch/80256EE600585943/%28httpPages%29/29B727532FECBE96C12571860035A6DB?OpenDocument>>. Also see, “Brief Description of Chemical Weapons,” OPCW. <<http://www.opcw.org/about-chemical-weapons/what-is-a-chemical-weapon/>> .

<sup>14</sup> Gigi Kwik Gronvall and Nidhi Bouri, "Biosafety Laboratories," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 6/4 (Dec. 31, 2008), pp. 299-308.

this tool is commonly used in biological research. Companies around the world provide DNA synthesis services, the cost of which has been steadily declining. It is currently possible to synthesize DNA segments for less than a dollar per base pair.

- **DNA sequencing** can be used to determine the nucleotide sequence for the genomes of organisms, ranging from viruses and bacteria to plants and animals. DNA sequencing technology has existed for more than 30 years, and sequence information is widely available on public online databases.

The largest public sequence database, GenBank, includes information about a wide range of organisms and a small subset of its entries represents pathogenic microbes.<sup>15</sup> GenBank is part of the International Nucleotide Sequence Database Collaboration (INSDC), which is maintained in collaboration with the DNA Databank of Japan and the European Molecular Biology Laboratory.<sup>16</sup> The database receives submissions from individual scientists who wish to share gene sequences featured in an upcoming publication and from large-scale sequencing centers that upload bulk submissions.

- **Synthetic Biology** has been defined by members of the research community as “the design and construction of new biological entities such as enzymes, genetic circuits, and cells or the redesign of existing biological systems.”<sup>17</sup> Synthetic biology aims to take an engineering approach to biology to produce new biological systems that do not exist in the natural world and to re-engineer existing biological components. The purpose of this research is both to advance our fundamental understanding of cellular processes and to engineer those processes to produce useful tools and materials.<sup>18</sup> For example, microbes are currently being engineered to produce liquid biofuels, with the aim of replacing petroleum-based fuels in transportation.<sup>19</sup>

Synthetic biology has the potential to bring about transformational advances in biological engineering, however recent developments in this field have led to concerns among the security policy and scientific research communities about the potential for malevolent use of this technology – in particular the ability to synthesize the genomes of viruses from scratch. As a result of these concerns, the synthetic biology community has worked to develop tools to manage these risks such as developing best practices for self-regulation among commercial synthetic DNA providers and building a culture of responsibility among synthetic biology researchers.<sup>20</sup>

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<sup>15</sup> GenBank. <<http://www.ncbi.nlm.nih.gov/genbank>>.

<sup>16</sup> International Nucleotide Sequence Database Collaboration. <<http://www.insdc.org/>>

<sup>17</sup> SynBERC, “What is synthetic biology?” <<http://www.synberc.org/content/articles/what-synthetic-biology>>

<sup>18</sup> “Synthetic Biology FAQ,” SyntheticBiology.org. <<http://syntheticbiology.org/FAQ.html>>

<sup>19</sup> Fuzhong Zhang, Sarah Rodriguez, Jay D. Keasling, “Metabolic engineering of microbial pathways for advanced biofuels production,” *Current Opinion in Biotechnology*, Volume 22, Issue 6, December 2011. <<http://www.sciencedirect.com/science/article/pii/S0958166911000875>>

<sup>20</sup> Michele S. Garfinkel, Drew Endy, Gerald L. Epstein, and Robert M. Friedman, “Synthetic Genomics: Options for Governance,” October 2007.



- **Dual-use.** The dual-use nature of biological research stems from the fact that the very same information, materials and technology that could be used to benefit humanity by providing advances in public health could also be used for malevolent purposes, such as biological weapons.

This dual-use dilemma is illustrated by a recent controversy over research on the H5N1 bird flu strain. Two independent studies, conducted in the Netherlands and in the United States, created a strain of H5N1 bird flu virus that could be potentially transmissible among humans. The naturally occurring H5N1 strain rarely infects humans, but has a very high reported fatality rate – more than 50 percent – for those infected.<sup>21</sup>

Two research groups created a strain of H5N1 flu virus that can be spread via airborne transmission among ferrets, an animal model that closely mimics the behavior of many types of flu viruses in humans. This change was caused by a handful of mutations in a small group of genes. The purpose of these studies was to determine if it is possible for a modified version of the H5N1 avian flu virus to cause a human pandemic and if so, to identify which genetic changes would be required to make the virus more transmissible among humans. This would alert researchers to potentially dangerous mutations in natural repositories of the virus, which could serve as a warning sign. Researchers also hoped that this research could lead to the discovery of antiviral drugs and vaccines.<sup>22</sup>

These studies sparked controversy in the bioscience research community. Some scientists in the influenza research community argue that it is crucial to learn more about H5N1 to protect against looming global public health threats, while others assert that this research should never have been conducted and have expressed concern that a terrorist group could use this information to engineer a deadly virus.<sup>23</sup> The US National Science Advisory Board for Biosecurity (NSABB) reviewed these studies and initially made the unprecedented recommendation to the journals *Science* and *Nature* to withhold experimental details – specifically regarding the genetic mutations – when publishing these studies. However, this guidance was subsequently contradicted by a WHO panel of experts who advocated full publication of the results and experimental methods. The NSABB revisited its

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<<http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-genomics-report/synthetic-genomics-report.pdf> >

<sup>21</sup> Donald G. McNeil Jr. and Denise Grady, “How Hard Would It Be for Avian Flu to Spread?” *New York Times*, Jan. 2, 2012. <<http://www.nytimes.com/2012/01/03/health/an-explanation-of-how-avian-flu-spreads.html?pagewanted=all>>

<sup>22</sup> *Ibid* and Denise Grady and William J. Broad, “Seeing Terror Risk, U.S. Asks Journals to Cut Flu Study Facts,” *New York Times*, Dec. 20, 2011. <<http://www.nytimes.com/2011/12/21/health/fearing-terrorism-us-asks-journals-to-censor-articles-on-virus.html?ref=health>>

<sup>23</sup> “Biosecurity Board Assessing Studies on Altered Bird Flu Virus,” *Global Security Newswire*. Dec. 1, 2011. <<http://www.nti.org/gsn/article/biosecurity-board-assessing-studies-altered-bird-flu-virus/>>

earlier decision and ultimately reversed it, recommending full publication of the results, and the papers were published by *Nature* and *Science* in 2012.<sup>24</sup>

This controversy over appropriate publication guidelines for dual-use research reflects the challenges of balancing the need for openness necessary for scientific research to protect public health with the necessity to prevent dangerous information from falling into the hands of those who would use it to cause harm. While the H5N1 issue has been resolved, similar controversies will continue to arise as advances in biotechnology push the limit of what is possible in academic research laboratories, and efforts to manage dual-use risks will become increasingly important and challenging.

## Major Challenges

There are major challenges for developing effective biosecurity measures internationally. The life sciences differ from nuclear science developments in that they are conducted around the world in commercial and academic laboratories and not exclusively at those belonging to national governments.<sup>25</sup> In addition to this wider scale of practice, the actual speed of scientific advancement and resulting security implications are “possibly too fast for any State, organization or individual to cover alone.”<sup>26</sup> Moreover, there are critical ambiguities surrounding the boundary between defensive and offensive biological programs<sup>27</sup>, which can be used to blur issues of legality (although it is clear under the Biological and Toxin Weapons Convention that the development of all biological weapons is illegal, as is their production, acquisition, transfer, retention, stockpiling and use).<sup>28</sup> Finally, in order to address the concerns of scientists, approaches aiming to promote a culture of biosecurity-based social responsibility need to be mindful to “ensure a focus on the highest-risk research and avoid unnecessary restrictions or censorship” over scientific freedom.<sup>29</sup>

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<sup>24</sup> Between Publishing and Perishing? H5N1 Research Unleashes Unprecedented Dual-Use Research Controversy <http://www.nti.org/newsroom/news/cns-issue-brief-dual-use-dilemma/>

<sup>25</sup> National Research Council (2006) *Globalization, Biosecurity, and the Future of the Life Sciences*, Washington, D.C.: National Academies Press. See chapter 3.

<sup>26</sup> Millet, P. (2010) The Biological Weapons Convention : Securing Biology in the Twenty-First Century, *Journal of Conflict and Security Law*. 15(1) pp. 25-43.

<sup>27</sup> Various ambiguities over the boundary between defensive and offensive biological programmes were also discussed by Susan Wright. WRIGHT, S. and KETCHAM, S. (1990b) The Problem of Interpreting the U.S. Biological Defense Research Program. In: WRIGHT, S. (Ed.) *Preventing a Biological Arms Race*. Massachusetts: The MIT Press, pp. 169-196. p. 186

<sup>28</sup> Biological and Toxin Weapons Convention. This was the first multilateral disarmament treaty banning an entire category of weapons. It opened for signature in 1972 and came into force in 1975.

<sup>29</sup> Smith, G., Davison, N., and Koppelman, B. (2010) “The Role of Scientists in Assessing the Risks of Dual-Use Research in the Life Sciences”, in John L. Finney and Ivo, Slaus. (eds.) *Assessing the Threat of Weapons of Destruction: The Role of Independent Scientists*. (NATO Science for Peace and Security Series E: Human and Societal Dynamics – Vol. 61) Amsterdam, IOP Press, p. 137.

## Evolution of the Biosecurity Threat with Technology Developments

With the accelerating advancement of life science technical capabilities, bio-scientists are continually pushing the limits of what is possible in the laboratory. These revolutionary developments in biotechnology can facilitate advances in basic research and the development of useful products, such as biofuels and pharmaceuticals. However, this technology could also be harnessed by those seeking to cause harm – a dual-use concern.

### a. Gene Synthesis and Sequencing: Rapid Technological Advances and Lower Costs

As discussed above, it is possible to chemically synthesize long DNA fragments in a test tube. Moreover, sequences for pathogen genes and genomes are widely available on public online databases such as GenBank<sup>30</sup> and the Comprehensive Microbial Resource.<sup>31</sup>

Synthesis of short DNA fragments has been possible for 30 years. The cost of gene synthesis has been dropping precipitously since the 1990s, falling from approximately \$30 per base pair to less than \$1 per base pair. During this time there have been significant improvements in gene synthesis productivity and accuracy. Likewise, the costs of DNA sequencing have continued to drop rapidly, while the accuracy and speed have increased.<sup>32</sup> (See Figure 5.)

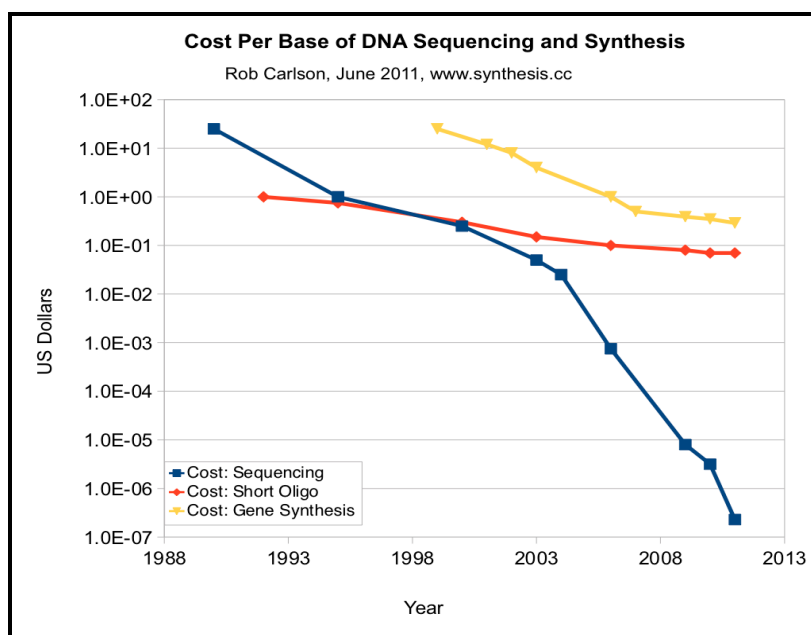


Figure 5. Declining costs of DNA Sequencing and Synthesis. (Rob Carlson.)

<sup>30</sup> Genbank. <<http://www.ncbi.nlm.nih.gov/genbank/>>

<sup>31</sup> Comprehensive Microbial Resource. <<http://cmr.jcvi.org/>>

<sup>32</sup> Rob Carlson, “New Cost Curves,” June 2011. <<http://www.synthesis.cc/2011/06/new-cost-curves.html>>. See also: Stephen Aldrich, James Newcomb, Robert Carlson, “Genome Synthesis and Design Futures,” 2007. <<http://www.bio-era.net/reports/genome.html>> and Rob Carlson, “The Pace and Proliferation of Biological Technologies,” 2003. <[http://www.synthesis.cc/writing/Carlson\\_Pace\\_and\\_Prolif.pdf](http://www.synthesis.cc/writing/Carlson_Pace_and_Prolif.pdf)>



## b. Synthetic Viral and Bacterial Genomes

With rapidly declining costs for DNA sequencing and synthesis, it is becoming easier to manipulate natural pathogens in ways that pose public health risks, and it is now possible to synthesize a virus from scratch without a natural template.

More recently, it has become possible to rapidly stitch those shorter pieces of DNA into longer fragments that comprise entire genes and even genomes. DNA synthesis technology was used to build the polio virus from chemical components in 2002<sup>33</sup> and to synthesize the 1918 Spanish influenza virus in 2005.<sup>34</sup> We now have the technology to synthesize any virus that infects humans, including very dangerous pathogens such as smallpox.<sup>35</sup> It is now possible to synthesize the genome of a medium-sized virus in a matter of weeks.<sup>36</sup>

Another significant milestone was reached in 2008, when researchers at the Venter Institute created the first synthetic bacterial genome.<sup>37</sup> In 2010 they successfully implanted a million-base-pair synthetic genome into a surrogate bacterial cell body, where it replaced the original DNA and brought the cell to life.<sup>38</sup>

While it is feasible in principle, *de novo* synthesis of pathogens is still difficult in practice. It is theoretically possible for a trained molecular biologist to make a deadly virus from scratch, but the tacit knowledge of viral synthesis procedures is not widespread. In practice, there are many opportunities to make small mistakes that lead to failure. However, over the next decade *de novo* synthesis may become the easiest way to obtain viruses with restricted distribution. Synthesis of bacterial pathogens may become more widely feasible in the long term.<sup>39</sup>

Concerns about the dual-use nature of synthetic genomics have led to a series of discussions about establishing an oversight mechanism to minimize the risk that DNA synthesis technology will be used to cause harm. They are primarily based on self-regulation among gene synthesis companies and the academic research community.<sup>40</sup>

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<sup>33</sup> Jeronimo Cello, Aniko V. Paul, and Eckard Wimmer, "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template," *Science*, 297/5583 (Aug. 9, 2002), pp. 1016-1018.

<sup>34</sup> Terrence M. Tumpey *et al.* "Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus," *Science*, Oct. 7, 2005: 310 (5745), 77-80.

<sup>35</sup> Drew Endy, "Reconstruction of the Genomes," *Science*, Feb. 29, 2008: 319 (5867), 1196-1197.

<sup>36</sup> Michele S. Garfinkel, Drew Endy, Gerald L. Epstein, and Robert M. Friedman, "Synthetic Genomics: Options for Governance," October 2007.

<sup>37</sup> Daniel G. Gibson, *et al.* "Complete Chemical Synthesis, Assembly, and Cloning of a *Mycoplasma genitalium* Genome," *Science*, February 29, 2008: 319 (5867), 1215-1220.

<sup>38</sup> Elizabeth Pennisi, "Synthetic Genome Brings New Life to Bacterium," *Science*, May 21, 2010: 328 (5981), 958-959.

See also, Daniel G. Gibson *et al.*, "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome," *Science* July 2, 2010: 329 (5987), 52-56.

<sup>39</sup> Michele S. Garfinkel, Drew Endy, Gerald L. Epstein, and Robert M. Friedman, "Synthetic Genomics: Options for Governance," October 2007, p. 13.

<sup>40</sup> *Ibid.* See also, Jonathan B. Tucker, "Double-Edged DNA: Preventing the Misuse of Gene Synthesis," *Issues in Science and Technology*, spring 2010. <<http://www.issues.org/26.3/tucker.html>>

Jocelyn Kaiser, "Proposed Biosecurity Review Plan Endorses Self-Regulation," *Science*, April 27, 2007:316 (5824), 529. <<http://www.sciencemag.org/content/316/5824/529.1.full>>

The US Department of Health and Human Services has also issued guidelines to DNA synthesis firms.<sup>41</sup> The ASEAN Regional Forum is also working on implementing guidelines to DNA synthesis firms in Southeast Asia.<sup>42</sup>

### Unique Risks Posed by Biological Agents

#### a. Widely dispersed materials and technology in civilian research laboratories worldwide

Research on potentially dangerous microbes is conducted at thousands of laboratories worldwide, and there is no full accounting of pathogens stored at each of these research sites. The United States alone has more than 1,400 facilities that work with or store select agents, which have been categorized by the US government as posing severe public health risks.<sup>43, 44</sup> Worldwide, dozens of BSL-4 and thousands of BSL-3 laboratories conduct research on dangerous pathogens that require high-containment facilities<sup>45</sup> – in addition to sites that store and work with pathogens without following BSL guidelines.

#### b. Pathogens exist in natural repositories in the environment.

While it is not technically trivial to do so, many pathogens can be isolated from the environment or from animal carrier reservoirs. For example, anthrax can be isolated from contaminated soil or infected livestock, and *Yersinia pestis*, which causes plague, can be isolated from infected rodents.<sup>46</sup>

#### c. Genome sequence information is publicly available, and public availability of this information is deemed crucial for ongoing advances in basic research and biotechnology development.<sup>47</sup> The genetic blueprints for pathogens are publicly available, and unlike in nuclear security, they cannot be classified because this

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Hans Bugl, *et. al.*, “DNA synthesis and biological security,” *Nature Biotechnology* **25**, 627 - 629 (2007).

<<http://arep.med.harvard.edu/pdf/Bugl07.pdf> >

<sup>41</sup> “Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA,” U.S. Department of Health and Human Services,

<<http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf> >

<sup>42</sup> Based on discussions at the 15th meeting of the Council for Security Cooperation in the Asia-Pacific (CSCAP) Study Group on Countering the Proliferation of Weapons of Mass Destruction, Sydney, Australia March 6-7, 2012.

<sup>43</sup> Jonathan B. Tucker, “Biosecurity: Limiting Terrorist Access to Deadly Pathogens,” *Peaceworks* 52, November 2003, p. 21.

<sup>44</sup> Select Agents and Toxins List.

<<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html> >

<sup>45</sup> Gronvall, G. K., & Bouri, N. (2008). Biosafety Laboratories. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 6(4), 299–308.

<sup>46</sup> Reynolds M. Salerno and Lauren T. Hickok, “Strengthening Bioterrorism Prevention: Global Biological Materials Management,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 5/2 (July 3, 2007), pp. 107-116.

<sup>47</sup> Committee on Genomics Databases for Bioterrorism Threat Agents, National Research Council (2004)

“Seeking Security: Pathogens, Open Access, and Genome Databases”

<<http://www.nap.edu/openbook.php?isbn=0309093058>>. See also, National Research Council (2007),

“Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities.”

<[http://www.nap.edu/openbook.php?record\\_id=12013&page=1](http://www.nap.edu/openbook.php?record_id=12013&page=1)>

information is deemed essential for basic biological research. While there is a risk that this sequence information could be used to produce a pathogen that could cause harm, the risks associated with restricting access to genetic sequence information are considered to be much worse, with the potential to stifle free and open research.

- d. Pathogens reproduce and mutate.** The ability of pathogens to reproduce and mutate has several implications for biosecurity. First, large stocks can be grown from small samples. This makes keeping track of pathogen stocks and inventories difficult and not a reliable means for detecting theft of material. The nuclear security approach of physical protection and materials control and accounting is therefore inadequate and not appropriate for biosecurity.<sup>48</sup> Second, naturally occurring mutations can help pathogens overcome the body's immune system, and pathogens can be deliberately engineered to defeat protective measures such as vaccines.

## Biosecurity Prevention and Response Spectrum

### Web of Prevention

Governments and professional communities of science, public health and security, such as the World Health Organization (WHO),<sup>49</sup> the Organization for Economic Cooperation and Development (OECD),<sup>50</sup> and the Biological and Toxin Weapons Convention (BTWC),<sup>51</sup> recognized the need for preventive and responsive measures, in a multifaceted manner, to mitigate the multi-dimensional threat posed by bioterrorism, biowarfare, and the potential advertent or inadvertent misuse of the life sciences. At the same time, it is critical to enhance global health security minimizing the “risks and dangers to health arising from global interactions among peoples and states. The global health security concept also sends the message that a nation's health security is intertwined with the rest of the world through the processes of globalization.”<sup>52</sup>

One way to take a multifaceted approach in practice has been conceptualized as the Web of Prevention (WoP) including: export controls; international and national responsive measures to biological and toxin weapons; biodefense capability; management of pathogens and toxins; public health; education and awareness-raising of life scientists, and international arms control mechanisms – particularly the Biological and Toxin Weapons Convention (BTWC).<sup>53</sup>

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<sup>48</sup> Tucker (2003) “Preventing the Misuse of Pathogens: The Need for Global Biosecurity.”  
<[http://www.armscontrol.org/act/2003\\_06/tucker\\_june03](http://www.armscontrol.org/act/2003_06/tucker_june03)>

<sup>49</sup>The World Health Organization, *Scientific Working Group on Life Science Research and Global Health Security: Report of the First Meeting*, Geneva: WHO, 2007.

<sup>50</sup>OECD, *Best Practice Guidelines on Biosecurity for BRCS*, Paris: OECD, 2007.

<sup>51</sup>United Nations, *Report of the Meeting of States Parties, BTWC/MSP/2008/5*, Geneva: United Nations, 2008.

<sup>52</sup> WHO. (2006) *Scientific working group on life science research and global health security*, WHO/CDS/EPR/2007.4, Geneva: WHO. p. 4

<sup>53</sup> British Medical Association, *Biotechnology, Weapons and Humanity* (London: Harwood Academic Publishers, 1999). British Medical Association, *Biotechnology, Weapons and Humanity* (London: BMA Professional Division Publications, 2004). International Committee of the Red Cross, *Biotechnology, Weapons and Humanity*, August 2003,  
<<http://www.icrc.org/Web/Eng/siteeng0.nsf/htmlall/bwh?OpenDocument>>. Graham S. Pearson, “Prospects

## Biosecurity Response Spectrum

Below are examples of four programs that are part of efforts to mitigate the effects of and respond to infectious disease outbreaks from natural causes or a deliberate attack.

### a. Global Disease Surveillance

The ProMED mail – the Program for Monitoring Emerging Diseases – plays a key role in monitoring infectious disease outbreaks worldwide. “ProMED-mail is an Internet-based reporting system dedicated to rapid global dissemination of information on outbreaks of infectious diseases and acute exposures to toxins that affect human health, including those in animals and in plants grown for food or animal feed. [...] By providing early warning of outbreaks of emerging and re-emerging diseases, public health precautions at all levels can be taken in a timely manner to prevent epidemic transmission and to save lives”

ProMED collects several types of information, including media reports, official reports and information from local observers, and rapidly disseminates information by posting reports on the program’s website and emailing them to more than 60,000 subscribers in at least 185 countries.<sup>54</sup>

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for Chemical and Biological Arms Control: The Web of Deterrence,” *Washington Quarterly* 16 (1993).  
Graham S. Pearson, “Why Biological Weapons Present the Greatest Danger,” paper delivered to the Seventh International Symposium on Protection against Chemical and Biological Warfare Agents, Stockholm, Norway, June 15-19, 2001. For the conceptual evolution of the WoP in those literatures, see the first chapter of Daniel Feaks, Brian Rappert and Catriana Mcleish, “Introduction: A Web of Prevention,” in Brian Rappert and Catriana Mcleish, eds., *A Web of Prevention: Biological Weapons, Life Science and the Governance of Research* (London: Earthscan, 2007).

<sup>54</sup> ProMED Mail. <<http://www.promedmail.org/aboutus/>>



Last update: 6 Aug 2012 06:00 | Next update: 6 Aug 2012 07:00

ProMED Mail Online Report, August 6, 2012

**b. Air Monitoring Stations: Early Detection of Airborne Biological Agents**

Rapid response to the release of biological agents in the environment requires early warning surveillance systems. For example, the US Department of Homeland Security (DHS) created a program called BioWatch, which uses sensors to detect bioaerosols in over 30 urban areas and at ‘events of significance,’ such as the Super Bowl.<sup>55</sup>

Following the 2001 anthrax attacks in the US, there was an increasing impetus for the scientific community to develop air monitoring stations that would rapidly detect the airborne release of biological agents without a high rate of false alarms.<sup>56</sup> There are inherent difficulties in developing accurate biological agent detection systems that can provide rapid results. One problem is that a successful system would require very high sensitivity due to the low dose threshold that could cause an infection to spread. Similarly, detection is difficult because the natural environment has a varied biological background that already contains many microbes. For this reason, an effective detection

<sup>55</sup> Testimony of Tara O’Toole Before the House Subcommittee on Homeland Security Appropriations, on Biosurveillance, U.S. Department of Homeland Security, Release Date: April 16, 2010.

< [http://www.dhs.gov/ynews/testimony/testimony\\_1271436311919.shtm](http://www.dhs.gov/ynews/testimony/testimony_1271436311919.shtm) >.

<sup>56</sup> “Defense Against Chemical and Biological Threats,” Sandia National Laboratories.

< <http://www.sandia.gov/mission/homeland/chembio/development/detection/index.html> >.

system has to use multiple molecular biology tests to verify the identity of a putative airborne biological agent.<sup>57</sup> The BioWatch surveillance system has faced technological and operational difficulties, including occasional false alarms, the inability of current systems to detect some pathogens of concern and long detection times.<sup>58</sup>

The current BioWatch system works by drawing in air samples from the environment, running them through a filter and testing for the presence of pathogens of concern. Under the current system, these filters are collected frequently and brought to a local lab for analysis. DHS plans to deploy the “Generation III” system, which automates sample analysis at the site of air sample collection, with the aim of reducing detection times from the current 12-36 hours down to 4-6 hours.

Testing for the presence of bioaerosols in the filtered air samples involves using standard molecular biology methods to test for the presence of DNA, protein and other materials. Analysis can also narrow down the range of possible biological agents by measuring particle size and sample pH.<sup>59</sup>

### **c. Medical Countermeasures**

Medical countermeasures (MCMs) are intended to provide protection and treatment for members of the population following a biological attack or epidemic.<sup>60</sup> Medical countermeasure programs include research and development, manufacturing, and stockpiling of vaccines that immunize against the most dangerous diseases or prophylactics to provide post-exposure treatment to victims.<sup>61</sup>

The development of MCMs requires government investment, since private industry does not currently have a financial incentive to invest in them. The United States began stockpiling MCMs to counter biological threats in the 1990s, and accelerated research and development in this area following the September 11 attacks. Almost \$6 billion have been allocated to Project BioShield, which includes development and stockpiling of anthrax vaccine, antitoxin, and antibiotics; smallpox vaccine; and botulinum antitoxin.<sup>62</sup> More recently, following the outbreak of H1N1 influenza, the federal government funded

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<sup>57</sup> Fatah, Alim et al. “Introduction to Biological Agent Detection Equipment for Emergency First Responders,” National Institute of Standards and Technology (NIST), United States, December 2001. <<https://www.ncjrs.gov/app/publications/abstract.aspx?ID=190747>>.

<sup>58</sup> “Homeland Security Official Rejects Reports Critical of Biowatch Program,” *Global Security Newswire*, July 13, 2012. <<http://www.nti.rsvpl.com/gsn/article/homeland-security-official-rejects-critical-reports-biowatch-program/>>. Also see, “Bio-Response Report Card,” Bipartisan WMD Terrorism Research Center, October 2011. <[http://www.wmdcenter.org/?page\\_id=183](http://www.wmdcenter.org/?page_id=183)>

<sup>59</sup> *Occupation Safety & Health Manual*, Occupation Safety & Health Administration, U.S. Department of Labor, June 24, 2008. <[http://www.osha.gov/dts/osta/otm/otm\\_ii/otm\\_ii\\_3.html#biological\\_agent\\_detection](http://www.osha.gov/dts/osta/otm/otm_ii/otm_ii_3.html#biological_agent_detection)>.

<sup>60</sup> Philip K. Russell and Gigi Kwik Gronvall. “Medical Countermeasure Development Since 2001: A Long Way Yet to Go,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, March 2012.

<sup>61</sup> “Project Bioshield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats,” *Government Accountability Office*, July 24, 2009. <<http://www.gao.gov/assets/100/96321.pdf>>.

<sup>62</sup> Office of the Assistant Secretary for Preparedness and Response, *Project Bioshield Annual Report to Congress* (Washington, DC: U.S. Department of Health and Human Services, 2010), pp. 2-6.



the development of vaccines, diagnostics, and antiviral drugs to combat the H1N1 influenza pandemic.<sup>63</sup>

**d. Microbial forensics as a tool for identifying the source material used in an attack**

Microbial Forensics is a means of identifying the source of a pathogen that has been deliberately dispersed in a biological attack. The aim is to trace the physical source of material with the ultimate goal of providing the international community and individual states with the ability to hold perpetrators accountable.<sup>64</sup>

Microbial forensics uses molecular biology tools to identify elements in a pathogen's genome and combines this with information from other physical and chemical assays, as well as traditional forensics methods, to trace the source of a microbe in question to a specific source. Microbial forensics was used extensively in efforts to identify the source material used in the 2001 US anthrax attacks; however, there is uncertainty about the accuracy of the conclusions of the investigation.<sup>65</sup> This is a relatively new field, and considerable resources have been invested in developing microbial forensics tools. The US established the National Bioforensic Analysis center in 2004, which is the lead agency for conducting technical microbial forensic analysis in support of US federal government investigations.<sup>66</sup>

## **The Biological and Toxin Weapons Convention (BTWC)**

“As a result of prolonged efforts by the international community to establish a new instrument that would supplement the 1925 Geneva Protocol, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, better known as the Biological Weapons Convention (BTWC), opened for signature on April 10, 1972. The BTWC was the first multilateral disarmament treaty to ban the production and use of an entire category of weapons. It entered into force on March 26, 1975. Over the intervening years, increasing numbers of States joined the Convention. There are currently 159 States Parties and 15 Signatory States. The BTWC effectively prohibits the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons and is a key element in the international community's efforts to address the proliferation of weapons of mass destruction.”<sup>67</sup>

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<sup>63</sup> Philip K. Russell and Gigi Kwik Gronvall. “Medical Countermeasure Development Since 2001: A Long Way Yet to Go,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, March 2012.

<sup>64</sup> “Microbial Forensics,” MITRE Corporation, May 2009.  
<<http://www.fas.org/irp/agency/dod/jason/forensics.pdf>>.

<sup>65</sup> Committee on Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 Bacillus Anthracis Mailings, *Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 Anthrax Letters* (Washington, DC: *The National Academies Press*, 2011).

<sup>66</sup> “National Biodefense Analysis and Countermeasures Center,”

<[http://www.dhs.gov/files/labs/gc\\_1166211221830.shtm](http://www.dhs.gov/files/labs/gc_1166211221830.shtm)>. Also see, Bruce Budowle, Steven E. Schutzer, Anja Einseln, Lynda C. Kelley, Anne C. Walsh, Jenifer A. L. Smith, Babetta L. Marrone, James Robertson, and Joseph Campos, “Building Microbial Forensics as a Response to Bioterrorism,” *Science*, 301/5641 (Sept. 26, 2003), pp. 1852-1853.

<sup>67</sup> Biological Weapons Convention Background Information.

### BTWC Main Articles

Article I	Never under any circumstances to acquire or retain biological weapons.
Article II	To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining.
Article III	Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons.
Article IV	To take any national measures necessary to implement the provisions of the BTWC domestically.
Article V	To consult bilaterally and multilaterally to solve any problems with the implementation of the BTWC.
Article VI	To request the UN Security Council to investigate alleged breaches of the BTWC and to comply with its subsequent decisions.
Article VII	To assist States which have been exposed to a danger as a result of a violation of the BTWC.

### BTWC Major Challenges:

The BTWC faces several challenges. First, it has no permanent implementing body; three staff members serve as a BTWC secretariat – the Implementation Support Unit (ISU),<sup>68</sup> which is currently funded by member states independent of UN funding. The Convention also lacks a verification mechanism, and there is no consensus as to whether a comprehensive BTWC verification regime is possible, given the widespread nature of biological research at thousands of sites worldwide and the dual-use dilemma. Third, dual-use issues blur the line between legitimate research and development for defense purposes, such as vaccine development, and R&D that crosses the line into offensive work for weapons development. Therefore, developing a transparency mechanism to maintain international confidence that national biodefense programs are conducting legitimate research is an ongoing challenge.

### Evolution of the BTWC: from verification to national measures

Recognizing the importance to further strengthen BTWC compliance, a group of governmental experts (VEREX) was established at the Third Review Conference (1991) to examine potential verification measures from a scientific and technical standpoint<sup>69</sup>. This work continued through the Ad Hoc Group (AHG), which was formed to consider possible verification measures and develop a legally binding verification protocol.<sup>70</sup> However in 2001, following a decade-long AHG meeting processes, BTWC states parties

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<[http://www.unog.ch/80256EE600585943/\(httpPages\)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument)>

<sup>68</sup> Biological Weapons Convention Implementation Support Unit. <[www.unog.ch/bwc/isu](http://www.unog.ch/bwc/isu)>.

<sup>69</sup> Pearson, Graham, "The Implementation of Legally Binding Measures to Strengthen The BWC." 2004.

<sup>70</sup> "BWC Ad Hoc Group Inches Forward," *Arms Control Today*, September 2000.

<<http://www.armscontrol.org/node/2870>>.



decided to shift their focus away from efforts to develop verification measures. Instead, states parties began to focus on evolving the treaty regime to enhance national implementation of the Convention, and to deal with a broader range of biological risks. The broader scope of risks included: biological weapons threats posed by states and non-state actors, laboratories with high-risk pathogens, and natural outbreaks of infectious diseases. As part of this process, the BTWC has expanded collaboration with international partners, including the World Health Organization (WHO), the World Organization for Animal Health (OIE) and the Food and Agriculture Organization (FAO) as well as the UN Security Council Resolution 1540. At the Sixth Review Conference in 2007, the Implementation Support Unit (ISU) was launched to assist states parties in meeting national implementation.<sup>71</sup>

### **Current Status:**

The seventh review conference was held in Geneva in December 2011. At the conference US Secretary of State Hillary Clinton addressed the challenges posed by the dual-use dilemma and the rapid development of biotechnology stating that “advances in science and technology make it possible to both prevent and cure more diseases, but also easier for states and non-state actors to develop biological weapons” and that “a crude, but effective, terrorist weapon can be made by using a small sample of any number of widely available pathogens, inexpensive equipment, and college-level chemistry and biology.”<sup>72</sup> Secretary Clinton also advocated for additional voluntary transparency measures among the BTWC states parties to build confidence in the Convention, and indicated that the United States would demonstrate its commitment to transparency by inviting several BTWC states parties to visit a US biodefense facility in 2012.<sup>73</sup> At the end of the conference, states parties also agreed on the need to enhance participation in voluntary confidence-building measures.

## **The Biosecurity Concept**

In this composition, efforts to mitigate and respond to the potential of destructive use of the life sciences at national, regional and international levels is broadly conceptualized as biosecurity, although the term ‘biosecurity’ has been defined differently internationally based on specific social and linguistic backgrounds.<sup>74</sup> This is a broader concept than that

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<sup>71</sup> “Disarmament News Archive,” United Nations in Geneva.

<[http://www.unog.ch/unog/website/disarmament.nsf/\(httpPages\)/4E7BB203FEACC8B5C1257219002E7C90?OpenDocument&unid=26BA69147DC74D3BC12571860036935C](http://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/4E7BB203FEACC8B5C1257219002E7C90?OpenDocument&unid=26BA69147DC74D3BC12571860036935C)>.

<sup>72</sup> Hillary Clinton, “Remarks at the 7th Biological and Toxin Weapons Convention Review Conference,” Dec. 7, 2011. <<http://www.state.gov/secretary/rm/2011/12/178409.htm>>.

<sup>73</sup> Elaine M. Grossman, “Clinton Urges more Reporting, Transparency on Biological Materials,” *Global Security Newswire* (Dec. 7, 2011). <<http://www.nti.org/gsn/article/clinton-urges-more-reporting-transparency-biological-materials/>>

<sup>74</sup> The term biosecurity has been defined in different concepts in different social and linguistic backgrounds in different countries. See Sunshine Project. (2003) ‘Biosafety, biosecurity, and biological weapons’, *Background paper on three agreements on biotechnology, health, and the environment, and their potential contribution to biological weapons control*, October 2003, [Electronic], Available: [http://www.natwiss.de/publikationen/Biosafety\\_and\\_Biosecurity.pdf](http://www.natwiss.de/publikationen/Biosafety_and_Biosecurity.pdf) [Jan. 17, 2010]; Fidler, D. and Gostin, L. L. (2007) *Biosecurity in the global age: Biological weapons, public health, and the rule of law*, CA: Stanford University Press.

often given to ‘laboratory biosecurity.’ The WHO definition of **laboratory biosecurity** refers to “institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.”<sup>75</sup>

### **Definitional Issues in Biosecurity: Asia Pacific Context**

The term biosecurity has been conceptualized differently across different scientific and professional disciplines. One study shows that the term has been used in ecology, agriculture, food supply, arms control and public health – albeit with different meanings and conceptualizations.<sup>76</sup> Therefore, when it comes to policy making on biosecurity, this overlaps with interdisciplinary areas such as biosafety, counter-terrorism, agricultural biosecurity and biodiversity.<sup>77</sup> In addition to these conceptual complications, biosecurity has also experienced linguistic complications. Although biosecurity and biosafety are different terms in English, when translated into Spanish, French and other Romance languages it becomes one word.<sup>78</sup>

In the Asia-Pacific region the concept of biosecurity has a strong tradition in agricultural biosecurity, biodiversity and public health rather than in security concerning dual-use issues (biological warfare or terrorism). A study shows that “75 percent of all emerging viruses over the past two decades have been zoonotic”,<sup>79</sup> and particularly in East Asia, the experience of SARS and Avian Influenza have given critical momentum for the regional governments to prioritize public health as a security issue.<sup>80</sup> Therefore, regional communities, such as the Association of South East Asian Nations (ASEAN) and the Asia-Pacific Economic Cooperation (APEC) have recurrently addressed the importance of coordinated policy making in public health and agricultural biosecurity.<sup>81</sup>

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<sup>75</sup>The WHO definition of laboratory biosecurity refers to “institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.” See World Health Organization. (2004) *op. cit.*, p. 47.

<sup>76</sup>The term ‘biosecurity’ has been defined in different concepts in different social and linguistic backgrounds in different countries. See Sunshine Project. (2003) ‘Biosafety, Biosecurity, and Biological Weapons’, *Background Paper on Three Agreements on Biotechnology, Health, and the Environment, and Their Potential Contribution to Biological Weapons Control*, October, Available from [http://www.natwiss.de/publikationen/Biosafety\\_and\\_Biosecurity.pdf](http://www.natwiss.de/publikationen/Biosafety_and_Biosecurity.pdf); Fidler, D. and Gostin, L. L. (2007) *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law*, CA: Stanford University Press.

<sup>77</sup>Barletta, M. (2002) *Biosecurity Measures for Preventing Bioterrorism*. CNS Publications, Available from <http://cns.mii.edu/research/cbw/biosec/index.htm>

<sup>78</sup> Sunshine Project. (2003) *op. cit.*, at p. 2.

<sup>79</sup>Mackenzie, J. (2007) ‘Emerging Viral Diseases in South-East Asia and the Western Pacific: the Importance of Biosecurity and the Dilemma of Dual-Use,’ presentation provided at the *Regional Biosecurity Workshop*, May, Singapore. Available from <http://www.cisssm.umd.edu/papers/index.php?docTitle=&author=&docNotes=&docType=&project=The%20Controlling%20Dangerous%20Pathogens%20Project> at p. 5.

<sup>80</sup> Enemark, C. (2007) *Disease and Security: Natural Plagues and Biological Weapons in Asia*, London: Routledge.

<sup>81</sup>For example, APEC defined biosecurity “as risk assessment measures and agricultural best practices taken to prevent the incursion of exotic agricultural pest.” See APEC. (2005) ‘Proposed Report and Recommendations,’ presented at the *APEC Symposium on Response to Outbreaks of Avian Influenza and Preparedness for a Human Health Emergency*, July 28-29, California, USA. at p. 2; ASEAN (2010)

This trend can be clearly found in a case study of New Zealand. Dunworth noted that:

[I]n New Zealand the terminology of biosecurity is avoided in security discourse [concerning bioterrorism], and explains this is partly due to the importance of biosecurity in the sense of protecting its agricultural sector, and partly due to a resistance to the rhetoric of terrorism.<sup>82</sup>

The author further argued that “[b]iosecurity is fundamental to New Zealand’s well-being and for that reason any attempt to use this terminology in the context of bioweapons is likely to continue to be resisted”.<sup>83</sup>

In order to better understand the conceptualisation of biosecurity in this region, it is also important to see how local life scientists perceive the potential risk associated with biotechnology research. For this question, a study that investigated the state of laboratory safety and security policies in 16 Asian countries gives useful insights. The study suggested the risk that most concerned practicing scientists was the scenario of pathogens under research “[a]ccidentally infecting people or animals or contaminating the environment outside laboratory,” rather than theft or advertent use of the agents for destructive purposes.<sup>84</sup> The study also showed that although scientists clearly recognize the possible risk of generating novel infectious agents, their concern was in relation to the accidental release.<sup>85</sup> Under the definition of the WHO, such accidental releases are recognized as safety issues rather than dual-use security issues.<sup>86</sup> Therefore, dual-use issues have a relatively low profile in the risk perception of life scientists – at least in some Asian countries.

## Biosecurity Legislation: Asia Pacific Context

Although dual-use issues are not the highest priority of traditional concepts of biosecurity in the region, dual-use issues are gradually becoming of interest for regional countries.<sup>87</sup> Particularly regional countries have been working on this issue under the BTWC.<sup>88</sup> Since

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*Strategic Plan of Action on ASEAN Cooperation in Food, Agriculture and Forestry*, Available from <http://www.aseansec.org/6218.htm>

<sup>82</sup>Dunworth, T. (2009) “Biosecurity in New Zealand,” in Rappert, B. and Gould, C. (eds.) *Biosecurity: Origins, Transformations and Practice*, Hampshire: Palgrave Macmillan, pp. 156-170 at p. 156.

<sup>83</sup> Ibid, p. 169.

<sup>84</sup>Gaudioso, J. (2006) *A Survey of Asian Life Scientists: The State of Biosciences, Laboratory Biosecurity, and Biosafety in Asia*, California: Sandia National Laboratories. Available from <http://prod.sandia.gov/techlib/access-control.cgi/2006/060842.pdf> p 25

<sup>85</sup>Ibid.

<sup>86</sup>WHO. (2004) *Laboratory Biosafety Manual*, Geneva: WHO, at p. 47.

<sup>87</sup>APEC. (2002) *Report of the ISTWG Ad Hoc Group Chair: Infectious Diseases and Other Health Issues*, Oct. 24, AMM/036, Mexico: APEC; More recently, the ASEAN Regional Forum (ARF) has been working on biological threat reduction concerning bioterrorism as a part of public health preparedness in cooperation with the BTWC Implementation Support Unit (ISU) of the UN Department of Disarmament Affairs (DDA), WHO, FAO and International Criminal Police Organization (INTERPOL). See AR. (2009) ‘Co-Chair’s Summary Report,’ presented at the *ASEAN Regional Forum Workshop on Biological Threat Reduction*, June 10-11, Manila, Philippines.

<sup>88</sup>Although Taiwan is not a member state of the United Nations, “the authorities on Taiwan state they will continue to abide by the provisions of the convention”. Arms Control Association. (2004) *The Biological Weapons Convention (BWC) At A Glance*, Available from <http://www.armscontrol.org/factsheets/bwc>

2003, the BTWC has conducted in-depth discussions on national implementation measures for the prohibition against biowarfare and bioterrorism. These discussions also included the capacity-building in public health preparedness, in cooperation with the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE).<sup>89</sup>

To pay careful attention to the public health issues under the BTWC is based on the growing understanding that there are policy overlaps in responding to and mitigating the effects of a natural outbreak of disease and also of a deliberately triggered outbreak of disease. To further enhance biosecurity norms and practice on dual-use issues, the BTWC developed specific discussions on education for biological scientists in 2008.<sup>90</sup>

Table 2 indicates the provisions of national legislation to implement the BTWC.<sup>91, 92</sup> There are certain types of national legislation in relation to the BTWC, such as where:

1. Existing national regulations are enough to achieve the scope of the BTWC and no further legislation is necessary,
2. Certain amendments of existing laws and regulations are necessary,
3. An act is newly enacted specifically for the BTWC, and
4. Broader legislation is enacted not only for the BTWC but generally for anti-terrorism acts.<sup>93</sup>

A commonly recognized approach of the countries from Asia-Pacific is to use, or make minor amendments of, existing laws and regulations related to hazard substances (toxins and pathogens), export control, criminal codes and public health.

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<sup>89</sup> United Nations. (2006) *Final Document. Sixth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*. BWC/CONF.VI/6, 8 December. Geneva: United Nations. Available from <http://www.opbw.org/>

<sup>90</sup>United Nations. (2008) *Report of the Meeting of States Parties*, BWC/MSP/2008/Dec. 5, 12, Geneva: United Nations. Available from <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G09/600/07/PDF/G0960007.pdf?OpenElement> at paragraph 26-27.

<sup>91</sup>National legislation is a process to domestically implement the norm of an international treaty within a specific legal system of a state. Since each country possesses a different legal system, it is understood that the implementation of specific regulations are left to the discretion of States Parties. Dunworth et al., explains the different legislative process between common law and civil law traditions in order to nationally implement the BTWC. See Dunworth, T. and McCormack, T. L, H. (2006) National Implementation of the Biological Weapons Convention. *Journal of Conflict and Security Law*, 11(1), 93-118.at p. 98.

<sup>92</sup>There has national legislation on biosecurity measures introduced by Centers for Disease Control (CDC), Taiwan. See <http://www.cdc.gov.tw/ct.asp?xItem=7806&ctNode=935&mp=5>; Biosecurity measures are laboratory biosecurity measures. The WHO definition of laboratory biosecurity refers to 'institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.' See World Health Organization. (2004) *Laboratory Biosafety Manual*, Geneva: WHO, at p. 47.

<sup>93</sup>Republic of Korea. (2003) *National Measures or Legislation to Implement the BTWC: A Conceptual Analysis*, BWC/MSP.2003/MX/WP16, Aug. 6, Geneva: United Nations. Available from [http://www.opbw.org/new\\_process/mx2003/bwc\\_msp.2003\\_mx\\_wp16.pdf](http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp16.pdf) at pp. 3-4.

However, at the meeting of the BTWC in 2003 Australia argued that such an approach:

... may be partly but not entirely effective for the purposes of the BTWC. Furthermore, such legislation is often quite narrow in scope - absencing some activities, facilities and materials - with several regulatory functions scattered between many government agencies.<sup>94</sup>

Indeed, some countries such as Australia, New Zealand, and the Republic of Korea developed their own national strategies and reported back to the BTWC in 2007.<sup>95</sup>

## Biosecurity Center: Asia Pacific Context

Due to the differences in definition of biosecurity, Australia has three different types of national biosecurity centers. One of them deals with dual-use issues and provides university level education programs for life scientists.<sup>96,97</sup> New Zealand has a governmental division of biosecurity on non-dual-use topics, working on the protection of public health and “the welfare of our environment, flora and fauna, marine life and Maori resources.”<sup>98</sup>

The Philippines and Thailand assign importance to national networking amongst relevant governmental and academic institutions for building the capacity of technical experts. The Philippines set up a steering committee on *National Laboratory Biosafety and Biosecurity Action Plan Task Force* in 2006.<sup>99</sup> The plan underlines the technical capacity-building and education for life scientists about public health and bioterrorism issues.<sup>100</sup>

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<sup>94</sup>Australia. (2003) *Model Strategy for Implementing BWC Obligations*, BWC/MSP.2003/MX/WP39, 22 August, Geneva: United Nations. Available from [http://www.opbw.org/new\\_process/mx2003/bwc\\_msp.2003\\_mx\\_wp39.pdf](http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp39.pdf) at p. 1-2.

<sup>95</sup>Australia. (2007) *Increasing the Technical Expertise of Law Enforcement Agencies to Assist Counter-Proliferation Initiatives*, BWC/MSP.2007/MX/WP12, Aug. 20, Geneva: United Nations. Available from [http://www.opbw.org/new\\_process/mx2007/bwc\\_mx07\\_WP.12\\_EN.pdf](http://www.opbw.org/new_process/mx2007/bwc_mx07_WP.12_EN.pdf); New Zealand. (2007) *Biosecurity-Protection from the Risks Posed by Organisms to the Economy, Environment People's Health Through Exclusion, Education and Control*, BWC/MSP.2007/MX/WP15, Aug. 21, Geneva: United Nations. Available from [http://www.opbw.org/new\\_process/mx2007/bwc\\_mx07\\_WP.15\\_EN.pdf](http://www.opbw.org/new_process/mx2007/bwc_mx07_WP.15_EN.pdf); Republic of Korea. (2007) *National Legislative Measures Adopted by the Republic of Korea to Implement the Biological Weapons Convention*, BWC/MSP.2007/MX/WP6, Aug. 14, Geneva: United Nations. Available from [http://www.opbw.org/new\\_process/mx2007/bwc\\_mx07\\_WP.6\\_EN.pdf](http://www.opbw.org/new_process/mx2007/bwc_mx07_WP.6_EN.pdf)

<sup>96</sup>University of Sydney and the Australian National University. *National Centre for Biosecurity*, Available from <http://www.biosecurity.edu.au/>

<sup>97</sup>The Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease deals with the protection of people, animals and the environment from infectious disease, pests and other biological threats. The website is available from <http://www.abrcrc.org.au/pages/About.aspx>; the other one is the Cooperative Research Centre for Plant Biosecurity. The website is available from <http://www.crcplantbiosecurity.com.au/>

<sup>98</sup>The Ministry of Forestry and Agriculture, *Biosecurity New Zealand*. See <http://www.biosecurity.govt.nz/>

<sup>99</sup>Republic of the Philippines Department of the Health Office of the Secretary. (2006) *Creation of a Steering Committee and Task Force / Technical Working Group for Health Sector on National Biosafety and Biosecurity Action Plan*, 15 September, Manila: Department of the Public Health. The document is available from the website of the Philippine Biosafety and Biosecurity Association (PHBBA) see <http://phbba.org/new2/index.html>

<sup>100</sup>Ibid.



Thailand has national networks on the capacity-building of biosafety and biosecurity experts to provide policy recommendations for the government. This effort includes the development of textbooks on the issue area, which is an important effort.<sup>101</sup> Surveys on biosecurity education in Europe and Japan indicated that one of the difficulties for university lecturers to promote biosecurity education was the lack of literature, which illustrates dual-use issues in the life sciences in a localized research context and in the local language.<sup>102</sup>

## Biosecurity Projects in Asia

Below are two examples of capacity-building projects in Asia designed to meet public health and biosecurity needs.

### Mekong Basin Disease Surveillance

The Mekong Basin Disease Surveillance (MBDS) network is a global health security network consisting of six Southeast Asian countries – Cambodia, China, Lao PDR, Myanmar, Thailand, and Vietnam – which was established in 1999 to promote regional information sharing on disease outbreaks and to improve regional outbreak response. The MBDS network aims to improve communicable disease outbreak detection, monitoring, and control and to reduce morbidity and mortality from outbreaks in the Mekong Basin region. Controlling contagious disease is a considerable challenge for MBDS member states, since thousands of people and animals cross their shared borders each day.<sup>103</sup> With support from the WHO, private foundations, industry, the U.S. Centers for Disease Control, and the United Nations, the network has made substantial contributions to successfully combating SARS and pandemic influenza in the region.<sup>104, 105</sup>

In 2001, the ministries of health of the MBDS member states signed a memorandum of understanding, which established “a legal and policy framework to facilitate the cooperation among partners in the implementation of the MBDS,” and a permanent coordination office was subsequently founded in Nonthaburi, Thailand. In 2007, a new and permanent memorandum of understanding among MBDS member states highlighted priority diseases including: dengue fever, malaria, SARS, and HIV/AIDS, in addition to other emerging infectious diseases, such as H5N1 influenza.<sup>106</sup>

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<sup>101</sup> Asia-Pacific Biosafety Association. (2009) ‘The Biosafety and Biosecurity Network of Thailand (BSNT)’, *A-PBA Newsletter*, 2(2), pp. 1-12.

<sup>102</sup> Revill, J., Mancini, G., Minehata, M. and Shinomiya, N. (2009) *op. cit.*

<sup>103</sup> Snider, K., “Mekong Basin Disease Surveillance Network Signs New Memorandum of Agreement at World Health Assembly,” *The Public Interest Newswire*, 2007. <[www.newswire.ascribe.org](http://www.newswire.ascribe.org)>.

<sup>104</sup> Mekong Basin Disease Surveillance Cooperation, “MBDS Granters and Partners,” [http://www.mbdsoffice.com/mbds\\_partners.php](http://www.mbdsoffice.com/mbds_partners.php).

<sup>105</sup> Innovative Support to Emergencies Diseases and Disasters, “Mekong Basin Disease Surveillance (MBDS) Network,” <http://instedd.org/network/mekong-basin-disease-surveillance-mbds-network/>

<sup>106</sup> Mekong Basin Disease Surveillance Cooperation, “The Extension of Memorandum of Understanding among the Health Ministries of the Six Mekong Basin Countries on the Mekong Basin Disease Surveillance,” 2007. <http://www.mbdsoffice.com/mou.php>

The network's activities include "epidemiologic training, cross-border exchange of information, joint epidemic response and investigation, and joint tabletop exercises on pandemic influenza preparedness."<sup>107</sup> In 2007, MBDS held its first regional pandemic influenza simulation exercise in Siem Reap, Cambodia. This tabletop exercise tested regional response capabilities to an influenza pandemic scenario and highlighted future challenges for the network, including: language, information and communication technology barriers between the communities, and further engagement and commitment throughout the region.<sup>108</sup>

### **UN Interregional Crime and Justice Research Institute CBRN Center of Excellence: Pilot Project in Southeast Asia**

The United Nations Interregional Crime and Justice Research Institute (UNICRI) and the European Union are jointly working to build a network of experts in chemical, biological, nuclear and radiological (CBRN) materials. This program plans to develop eight regional networks – throughout Asia, the Middle East, and Africa – and the initial pilot project is based in Southeast Asia.<sup>109</sup> The institute's aim is to build national and regional capacity, improve CBRN coordination and leverage existing resources and expertise. UNICRI's regional biosecurity capacity-building efforts will focus on six areas: 1) promoting knowledge development and sharing of biosecurity and biosafety best practices, 2) biological waste management, 3) biosecurity and biosafety guidelines and practices, 4) reinforcing international and national biosecurity legislation, 5) strengthening laboratory biosafety and biosecurity, and 6) establishing an international network of universities and institutes to raise awareness about dual-use concerns in biotechnology.<sup>110</sup>

These centers of excellence are intended to provide tailored assistance to non-EU member states by matching needs to assistance.<sup>111</sup> UNICRI first requests that partner states conduct a self-assessment; based on the results, individual countries can identify gaps and outline areas for engagement with CBRN experts. For example, in Southeast Asia, UNICRI and the EU have initiated a project with Malaysia, Laos, Cambodia,

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<sup>107</sup> Kimball, A., Moore, M., French, H., Arima, Y., Ungchusak, K., Wibulpolprasert, S., Taylor, T., Touch, S., Leventhal, A., "Regional Infectious Disease Surveillance Networks and their Potential to Facilitate the Implementation of the International Health Regulations," *Medicinal Clinics of North America*. November 2008.92:6. P 1459-1471.

<sup>108</sup> "Southeast Asian Nations Conduct Joint Exercise in Cambodia to Improve Flu Pandemic Response," *Global Security Newswire*, March 14, 2007. <<http://www.nti.org/newsroom/news/southeast-asian-nations-conduct-joint-exercise>> Also see, Moore M, Dausey D. Regional Pandemic Influenza Tabletop Exercise After Action Review. Bangkok: MBDS, 2007. <[http://www.mbdsoffice.com/data210308/regional\\_aar\\_final\\_2007\\_05\\_18\\_rev\\_2011\\_03\\_16.pdf](http://www.mbdsoffice.com/data210308/regional_aar_final_2007_05_18_rev_2011_03_16.pdf)>.

<sup>109</sup> Servais, Phillipe, "Instrument for Stability CBRN Risk Mitigation (Center of Excellence initiative)," powerpoint presentation, European Aid Cooperation Office, December 2009. <[www.episouth.org/outputs/presentations/Servais.pdf](http://www.episouth.org/outputs/presentations/Servais.pdf)>

<sup>110</sup> Speech, UNICRI Deputy Director, Biological Weapons Convention, Seventh Review Conference. <[http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/AEF2A3BF88F1D910C12579C9003BAA57/\\$file/UNICRI.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/AEF2A3BF88F1D910C12579C9003BAA57/$file/UNICRI.pdf)>

<sup>111</sup> Nexon, Elisande, "Strengthening the BTWC Through Laboratory Best Practices and Biosecurity," *Non-Proliferation Papers*, EU Non-Proliferation Consortium, No. 3, December 2011.

Vietnam and Brunei Darussalam to assess existing national and regional biosecurity and biosafety legislation and regulations.<sup>112</sup>

UNICRI emphasizes the requirement for shared responsibility among all stakeholders – scientists, technologists, policymakers, and the general public – rather than promoting a policy of technology denial through the employment of traditional international arms control measures. UNICRI notes that, unlike nuclear technology, which is verifiable and controllable through traditional arms control approaches, modern biotechnology is “prolific, cheap, and dual-use in nature.” This reality necessitates an approach that promotes shared responsibility for managing the technology.<sup>113</sup>

## Codes of Conduct and Bioethics

Codes of conduct, ethics, or practice are “non-legislated guidelines which one or more organizations and individuals voluntarily agree to abide by, that set out the standard of conduct or behavior with respect to a particular activity.”<sup>114</sup>

The Indonesian Academy of Sciences (API) has been designing a national code on biosecurity relevant to the Asia-Pacific context.<sup>115</sup> The rationale for such a code was concisely summarized in the report of the US National Research Council titled *Biotechnology Research in an Age of Terrorism*, in 2004:<sup>116</sup>

“Whether mandatory or voluntary, the adoption of codes of conduct by professional organizations or national academies of science, and the integration of ethics education into the training of students should serve to sensitize ‘young scientists to reflect on the wider consequences of their intended field of work.’”<sup>117</sup>

The Indonesian’s code is planned to be “incorporated into core curriculum for the biological sciences throughout Indonesia,” that is it is possibly to be made mandatory.<sup>118</sup> If this takes place, it will produce a rapid increase in awareness amongst life scientists about dual-use biosecurity issues.

## Bioethics

“The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research.

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<sup>112</sup> CBRN Centers of Excellence Project 12, Nov. 28, 2011.

< [http://www.cbrn-coe.eu/ProjectProposalDocuments/Project\\_012.pdf](http://www.cbrn-coe.eu/ProjectProposalDocuments/Project_012.pdf) >

<sup>113</sup> EU CBRNE COE website, accessed on June 18, 2012. < <http://www.cbrn-coe.eu/AboutCoE.aspx> >.

<sup>114</sup> WHO\_CDS\_EPR\_2006\_6 pdf p. iv

<sup>115</sup> Sudoyo, H. (2010) ‘Indonesia and the Global Challenges of Biological Control: From Jakarta to Geneva,’ presented at the *Workshop on “The Global Challenge of Biological Controls,”* April 8-9, UNIDIR, Geneva, Switzerland.

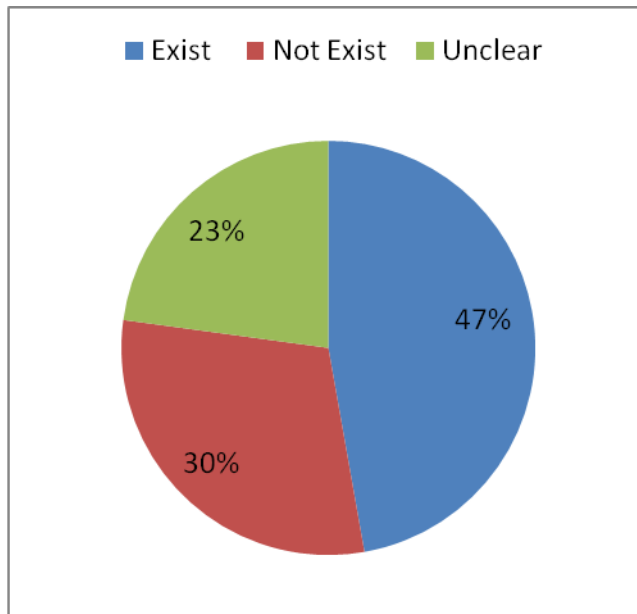
<sup>116</sup> National Research Council. (2004) *op. cit.*

<sup>117</sup> *Ibid.*, at p. 55

<sup>118</sup> Sudoyo, H. (2010) *op. cit.*, at p. 15



In this document, bioethics is one of the three components that contribute to a successful biorisk management culture.”<sup>119</sup>



### Bioethics: Asia Pacific Context

A study indicated that this was the most prevalently implemented topic in the survey – being provided by 47 percent of investigated degree courses.<sup>120</sup> Also, as the Figure suggests, this was a topic that has been implemented at universities in all the countries of the investigation.<sup>121</sup> There are three trends in terms of the content of bioethics education in Asia-Pacific. Firstly, many biomedical faculties are providing traditional medical ethics, such as the Declaration of Geneva of 1948, the Hippocratic Oath and the Declaration of Helsinki of 1964 for medical professionals,<sup>122</sup>

as well as contemporary topics such as ethics in stem cell and human embryo research. However, there was one case where the issue of dual-use was illustrated as part of ethics education, *Bioethics* (PAAE 8007), at the Australian National University.

Second, what is noteworthy in the ethics education of this region was the diverse range of cultural and religious traditions in ethics education for life scientists. For example, a Department of Biology in the Philippines provides mandatory *Catholic Theology* for the second and fifth year biology students. A Graduate School in Thailand provides *Buddhist Ethics* for the consideration of ethical challenges in medical sciences. Moreover, at a Department of Science and Technology Studies and a faculty of Biomedical and Health Science Engineering in Malaysia the following courses are provided – *Philosophy of Islamic Science, Science Technology in the Contemporary Islamic World, and Islamic and Current Issues*. Finally, at a College of Medicine in Taiwan, *Chinese Medical Ethics* is part of a core teaching strategy.

<sup>119</sup> WHO. (2006) *Biorisk Management: Laboratory Biosecurity Guidance*, WHO\_CDS\_EPR\_2006\_6, Geneva: WHO. p, iii

<sup>120</sup> Minehata, M. (2010) ‘An Investigation of Biosecurity Education for Life Scientists in the Asia Pacific Region,’ *Research Monograph for the Wellcome Trust Project on Building a Sustainable Capacity in Dual Use Bioethics*. Exeter and Bradford: University of Exeter and University of Bradford. Available from [http://www.internationalbiosafety.org/english/pdf/BioSec\\_AP\\_MM.pdf](http://www.internationalbiosafety.org/english/pdf/BioSec_AP_MM.pdf)

<sup>121</sup> Australia, India, Indonesia, Malaysia, New Zealand, South Korea, Singapore, Thailand, and Taiwan. Studies on China and Japan are available from Brian, Rappert. (ed.)(2010) *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, Canberra: Australian National University E Press. Available from: [http://epress.anu.edu.au/education\\_ethics.html](http://epress.anu.edu.au/education_ethics.html)

<sup>122</sup> World Medical Association. (2008). *op. cit.*

Third, alongside the highly localized ethical disciplines, there is an ethical and philosophical consideration to harmonize trans-cultural or regional ethics. For example, the course *Bioethics in Asia*, at a School of Medicine in Singapore, is provided for the students in biomedical ethics to develop “critical reflection on ethical concepts from a perspective of cultural differences and universal moral values.”<sup>123</sup>

### **Bioethics Network: Asia Pacific Context**

Ethics is an essential intervention point to promote in the education for life scientists.<sup>124</sup> Miller and Selgelid explain that scientific research generates a dual-use dilemma “since it is about promoting good in the context of the potential for also causing harm... [and a] dual-use dilemma is an *ethical* dilemma, and an ethical dilemma for the *researcher* as well as for those (e.g., governments) who have the power or authority to assist or impede the researcher’s work.”<sup>125</sup> As it was also noted in the introduction of this report, ethics education was recommended as a practical platform to promote dual-use topics for scientists in the current educational environments in Europe, Japan, and the United States.

In this view it is important to see the extent of the presence of national networking and academic associations on bioethics in Asia-Pacific. Table 2 also shows that some countries have institutionalized national advisory boards or committees. Amongst these, the Indonesian National Bioethics Commission is noteworthy as it deals with dual-use topics. Concerning the biosecurity issues, the commission provides policy recommendations to the government, domestic industry and scientific communities and plays the role of a hub for international policy coordination on ethics issues between WHO-Department of Health, FAO – Department of Agriculture and UNESCO – Indonesian Institute of Sciences (LIPI).<sup>126</sup> The necessity for capacity-building of the Commission about the BTWC has also been recognized.<sup>127</sup>

Having looked at the national policy trends of regional countries, this section showed that biosafety regulations were prevalent. Bioethics networking was also well developed in regional countries and there was a development in legislation and institutionalization on

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<sup>123</sup>The course details are available from [http://cbme.nus.edu.sg/edu\\_postgrad.htm](http://cbme.nus.edu.sg/edu_postgrad.htm)

<sup>124</sup>Traditionally enhancing the ethical principles “never do any harm” with scientific knowledge has long history in medical science, including the Hippocratic Oath and the Declaration of Helsinki of 1964 for medical professionals. Recently, the WHO study group on dual-use issues and ethical responsibility of life scientists argued that “to do no harm” principle in medical ethics is not enough but what is necessary is to take “a much more proactive role in controlling the hazards associated with the misuse of genomics for biowarfare”. WHO. (2005) *Life Science Research: Opportunities and Risks for Public Health Mapping the Issue*, WHO/CDS/CSR/LYO/2005.20, Geneva: WHO. at p, 6; See also WHO. (2002) *Genomics and world health. Report of the Advisory Committee on Health Research*, Geneva: World Health Organization.

<sup>125</sup>Miller, S. and Selgelid, M. J. (2007) “Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Science,” *Science and Engineering Ethics*, 13(4), pp. 523-580.

<sup>126</sup>Samihardjo, I. (2007) ‘Strengthening Oversight Over Dual Use Research In Asia: Indonesian Perspective,’ presented at the *Regional Biosecurity Workshop*, December, Bangkok, Thailand, Available from <http://www.cissm.umd.edu/papers/index.php?docTitle=&author=&docNotes=&docType=&project=The%20Controlling%20Dangerous%20Pathogens%20Project> at p. 20.

<sup>127</sup>Ibid.

biosecurity policies. However, this section also illustrated the low level of risk perception among practicing scientists about dual-use biosecurity issues. There is a clear gap between the presence of governmental policies and the lack of risk perception among scientists.

One reasonable explanation for this gap is the lack of education about the issue of biosecurity. Hypothetically, if there is a lack of specific provisions for biosecurity education at university level courses, it is natural that scientists are not aware about possible dual-use risks in their research. To further develop the understanding on this point, the next section focuses on the current state of biosecurity education at university level life science degree courses in the Asia-Pacific.

## Biosecurity Education

Biosecurity education is widely envisaged as a process to better inform understanding of how the potential for the misuse of the life sciences can be prevented. Specifically, it includes themes such as: *inter alia*; the dual-use risks in contemporary life science; responsible research conduct and ethics of life scientists; the history of biological-warfare programs and biological terrorism; the role of the international prohibition regimes and their national implementation;<sup>128</sup> intersection of public health and national security; and building an effective set of preventative policies to ensure benign development of the life sciences. A number of international educational efforts are already underway, as well as encouraging new initiatives.<sup>129</sup>

### List of Selected Educational Materials/Programs\*

Institution	Type	Level	Contents Description
Federation of American Scientists <sup>130</sup>	Online (Text)	University	6 case studies in dual-use including: synthesizing Polio; Aerosol Drug Delivery; Unexpected results in virus research; experiments in antibiotic resistance and Genetic control with RNA interference.
Southeast Regional Center of Excellence for Emerging Infections and Biodefence <sup>131</sup>	Online (Text), Group Discussion	University	5 units including: defining dual-use; case study of dual-use research publication; rules governing research and ethical analysis. Plus follow-up (Discussions)

<sup>128</sup> Such as BTWC of 1972, Chemical Weapons Convention of 1993 or Geneva Protocol of 1925.

<sup>129</sup> Brian, Rappert. (ed.)(2010) *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, Canberra: Australian National University E Press. Available from: [http://epress.anu.edu.au/education\\_ethics.html](http://epress.anu.edu.au/education_ethics.html)

<sup>130</sup> Federation of American Scientists. (2009) *Case Studies in Dual Use Research* Available from: <http://www.fas.org/biosecurity/education/dualuse/index.html>

<sup>131</sup> Southeast Regional Center of Excellence for Emerging Infections and Biodefence. (2008) *Online Module: The Dual Use Dilemma in Biological Research*. Available from: [http://www.serceb.org/modules/serceb\\_cores/index.php?id=3](http://www.serceb.org/modules/serceb_cores/index.php?id=3)

Center for Arms Control and Non-Proliferation <sup>132</sup>	Online (Video)	University	5 units: threat of BW; history of BW; peril of BW; prevention of hostile use and ethical reflection
George Mason University <sup>133</sup>	Academic Course	Graduate Program (MA, Ph.D.)	Biodefense (Ph.D.: 21 credit lectures, 1 Seminar and dissertation): Threat analysis; biodefense policy; preparedness; research methods, International Politics
University of California Institute on Global Conflict and Cooperation <sup>134</sup>	Seminar (2 weeks)	University, Industry	Biothreats learning program: risk-scenario planning and analysis; international coordination to risk reduction; growth of biotech industry
NOVA (TV program) <sup>135</sup>	Online (Text and FlashPlayer)	Public	4 main units: history of BW and global guide to BW; future germ defenses teacher's guide; making vaccines and agents of bioterror
Kings Center for Visualization of Science <sup>136</sup>	Online (Text)	Public	Raising awareness program for Chemical Weapons and the CWC
MIT Professional Education Program <sup>137</sup>	Short Course (3 days)	Public	Combating bioterrorism/policies of biosecurity including: Case studies; public health approach; law enforcement and barriers to bioweapons
Nuclear Threat Initiative <sup>138</sup>	Online (Text)	Public	Bioterrorism tutorial 6 units including: Introduction to BW terror; case analysis; BW agents; BW terrorism threat assessment, prevention and response
University of Pittsburgh Medical Center <sup>139</sup>	Online (Video: Role Play)	Public	Scenario based role-play simulation on the case of bioterrorism with smallpox
University of Bradford, UK	Online: University accredited Train the Trainer program	Public	Dual-use biosecurity, bioethics approaches, bioterrorism/policies of biosecurity including international prohibition regimes and scenario based studies for practicing scientists.

\***Note:** this list was created from data from the Federation of American Scientists. Available from <http://www.fas.org/programs/bio/educationportal.html>

<sup>132</sup>Center for Arms Control and Non-Proliferation. (2007) *Biosecurity: Risks, Responses, and Responsibilities* [Online]. Available from:

[http://www.armscontrolcenter.org/policy/biochem/biosecurity\\_educational\\_materials/](http://www.armscontrolcenter.org/policy/biochem/biosecurity_educational_materials/)

<sup>133</sup>George Mason University. (2008) *Biodefense Graduate Program*. Available from:

<http://pia.gmu.edu/grad/biod/>

<sup>134</sup>University of California Institute on Global Conflict and Cooperation Public Policy and Biological Threats. (2004, 2005, 2006, 2007) *A program of the UC Institute on Global Conflict and Cooperation*. Available from: <http://igcc.ucsd.edu/cprograms/PPBT/PPBT.php>

<sup>135</sup>NOVA. (2001) *NOVA Online: Bioterror* Available from: <http://149.48.228.121/wgbh/nova/bioterror/>

<sup>136</sup>Kings Center for Visualization of Science. (2005) *Raising Awareness: Multiple Uses of Chemicals and the Chemical Weapons Convention IUPAC Project 2005-029-1-050* Available from:

<http://www.kcvs.ca/multiple/index.html>

<sup>137</sup>MIT Professional Education Program. (2009) *Pandemics and Bioterrorism: From Realistic Threats to Effective Policies* Available from: [http://web.mit.edu/mitpep/pi/courses/combating\\_bioterrorism.html](http://web.mit.edu/mitpep/pi/courses/combating_bioterrorism.html)

<sup>138</sup>Nuclear Threat Initiative. (2004) *BT Terrorism Tutorial* Available from:

[http://www.nti.org/h\\_learnmore/bwtutorial/index.html](http://www.nti.org/h_learnmore/bwtutorial/index.html)

<sup>139</sup>Center for Biosecurity. (2006) *Atlantic Storm Interactive* University of Pittsburgh Medical Centre. Available from: <http://www.atlantic-storm.org/flash/index.htm>

## About the Authors

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**Ms. Zhiyuan Karen Lu** holds a BA in History and International Studies from the University of Idaho. She also holds an MA in Political Science from California State University, Chico. Currently, she is a graduate research assistant at the Center for Nonproliferation Studies where she is pursuing an MA in Nonproliferation and Terrorism Studies. Her primary research interests include regime culture and ethnic disputes in East Asia and how they influence security in that region, as well as broader issues related to nuclear security and US involvement in the Asian region. Throughout Karen's academic life, she had been an active participant of the Model United Nations conferences.

**Dr. Masamichi Minehata** was a SPF fellow at the Pacific Forum CSIS. He was awarded a PhD at the University of Bradford's Department of Peace Studies in July 2010 on the issues of Biological Weapons Convention (BWC). Previously, his primary research focus has been to promote global biosecurity education for life scientists under the auspices of the UK Prime Minister's Initiative on International Education (awarded by the British Council, UK).

**Ms. Jaime Yassif** is a doctoral candidate in the Biophysics Group at UC Berkeley. She is conducting her thesis research on the biophysics of transport processes in cells. Jaime holds an MA in Science and Security from the War Studies Department at King's College London, where she wrote her thesis on verification of the Biological Weapons Convention. She received her BA in Biology from Swarthmore College. Prior to her graduate work, Ms. Yassif worked for several years in science and security policy at the Federation of American Scientists and Nuclear Threat Initiative.