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Safety and Security in the Biotechnological Age

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GCSP

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Note: This report reflects the views of independent experts which are not always consensus views nor necessarily reflect the views of the sponsors of this seminar.

Introduction

In many ways, the world is at the beginning of what some are already calling the "Biological Century." Discoveries in the life sciences have the potential to reshape the worlds of health, food production, energy, and climate change, to produce new fuels, heat- and drought-resistant food crops, and to eradicate deadly diseases. But biotechnological discoveries also have a dark side – potential immense harm may be caused through accidental or intentional release of designer pathogens. The globe is also facing a myriad of natural biological threats. Fifteen million people die each year of deadly infectious diseases, with new ones emerging every year, such as Severe Acute Respiratory Syndrome (SARS) and Avian Flu. In a world of 700 million international air passengers yearly, and almost all on flights shorter than the incubation period of infectious diseases, national health has become only as safe as global health.

The challenge to biological security is two-fold. First, developed and developing countries alike must benefit from a strong global public health regime that controls disease outbreaks and builds local capacity to sustain the health of their citizens. Effective public health is also crucial against the threat of bioterrorism. Given the global diffusion of dangerous techniques and substances, prevention will be difficult and

therefore defences in both global and local public health systems must be robust.

The International Health Regulations (IHR-2005) of the World Health Organization (WHO) stipulate state responsibilities in the strengthening of national and global disease surveillance and response. What is needed now is full implementation of these regulations and the building of local health capacity in the developing world. A global initiative by key governments, in conjunction with leaders from the private sector, can ensure that global reaction is swift and supports local capability in cases of deadly infectious disease occurrence. This is a win-win opportunity for development and security.

Second, there is a need to promote the promising side of biotechnology and to protect against its 'dark side'. In the long run, a new regime for biotechnology safety and security must to be introduced. The existing international regime to stop biological weapons, the Biological and Toxic Weapons Convention (BTWC), is too slow and state-centric to address the dark-side uses of biotechnology. With tens of thousands individuals working in industry, research, and university labs in every part of the world, such a regime must engage industry, science, and the public. Intermediate steps can contribute to creating scientific consensus and international trust in order to spur collective action. An Intergovernmental Panel on Safety of Biotechnology akin to the body that generated international scientific consensus around climate change (the Inter-governmental Panel on Climate Change or IPCC), could bring together scientists from around the world to forge consensus about the trajectory of biotechnology risks and solutions thereto.

To discuss the current status of the security of biotechnology and to analyse the creation of possible structures and institutions to better serve the current biosecurity regime, the Geneva Centre for Security Policy (GCSP) hosted an international policy workshop entitled "The Safety and Security of Biotechnology" on 25 June 2009. The workshop

was jointly organised with the support of the Managing Global Insecurity Project (MGI), a partnership managed by the Center for International Security and Cooperation (CISAC) at Stanford University, the Center on International Cooperation at New York University and the Brookings Institution. The goal of MGI is to provide recommendations and to generate the momentum required to rebuild the global partnerships and international institutions needed to meet 21st-century trans-border challenges and threats. Among those threats, high on the international security agenda are the risk of spread of diseases caused by natural, accidental or deliberate events, including the misuse of biology or biotechnology, up to the use of biological weapons. Further support from the Governments of Switzerland and Norway is hereby acknowledged.

The issue of advances in biotechnology has received much attention from the international community. Under former United Nations (UN) Secretary-General Kofi Annan, it was highlighted in the High-Level Panel Report on Threats, Challenges and Change,[1] published in 2004. In addition, current Secretary-General Ban Ki Moon called a meeting on the subject in September 2009. The organisers of this GCSP workshop wished to contribute to the ongoing discussion among governments and policymakers with regard to the following imperatives:

- Raising awareness about this threat, and
- Strengthening multi-stakeholder and international cooperation to assess it and respond to it.

In a restricted setting, this workshop made it possible for high-level international experts to engage in a direct dialogue with policymakers, addressing the above-mentioned imperatives, to formulate recommen-

1 United Nations, A More Secure World: Our Shared Responsibility, Sept. 2004, available at: http://www.un.org/secureworld/.

dations for the improvement of existing national and multilateral regulations and structures.

Workshop Findings

Presentations and ensuing discussions at the workshop yielded the following general findings:

1. Advancements in the field of biological research are moving faster now than ever before.

2. At the same time, these biological innovations have a 'dual use'[2] potential of which researchers may not be aware. While on the one hand they may provide solutions to many of the world's problems, on the other hand they may potentially be abused, mishandled or used for hostile purposes.

3. As a result of these possible 'dark' uses of biotechnology, it is imperative that a dynamic international regime be put in place to meet, in a comprehensive manner, the multi-layered aspects of the new security challenges that biological advances now pose.

4. The current international regime, led by the Biological and Toxin Weapons Convention (BTWC), has succeeded in setting normative standards governing non use by states of biological weapons in warfare. However, these shall soon be insufficient to cope with the rapid and momentous changes expected in the field of biotechnology in this century.

5. The new regime must bring together the fields of industry, science and various non-governmental organisations (NGOs) to build together an effective web of response to the dark potentialities of biotechnology advances.

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2 United Nations, A More Secure World: Our Shared Responsibility, Sept. 2004, available at: http://www.un.org/secureworld/.

6. Such a web implies a network of different solutions and organisations to tackle the problem. Indeed, there is no one single 'magic' solution to combating the multi-faceted nature of biological research advances, and the coordinated international response must reflect this.

Introduction to the Biotechnological Century

A. The History of Biotechnological Development and the Significance of the 21st Century

Historically, the instances of bioterrorism have been few. Indeed, some experts believe that, at the present time, it would be incredibly difficult for a bioterrorist to carry out a large-scale, sophisticated attack. Though smaller-scale attacks could be possible against a specific target, such as releasing strains of foot-and-mouth disease in a cattle yard, to date there has been no historical record of such seemingly simple attacks. Some experts believe that this is due to the complex acquisition process necessary for the most destructive agents. This has led some experts to suggest that biological weapons are not only difficult for terrorists to use, but also that up to now, terrorists have not shown evidence of much interest in using them.

However, many experts believe that bioterrorism could become much more significant in the coming decades. Recent theories regarding the changing nature of warfare, such as those put forward by General Rupert

Smith on the idea of 'war amongst the peoples',[3] strengthen the belief that this ideational shift of the concept of war, when paired with the advances of biotechnology, could lead to greater instances of bioterrorism in the future. The changes observed in the field of biotechnology, with greater access available to more individuals, means that there could be more material available to be procured in the coming decades.

Yet most experts still believe that the gravest challenge at present may come from rogue individuals with access to high-containment laboratories (as was the case in the 2001 anthrax attack in the US). Moreover, such experts argue that most observed incidents of terrorist and criminal use of non-conventional agents have been carried out with chemical, radiological and toxin agents, as opposed to nuclear or biological ones. This, they argue, is because these agents are easier to acquire, with many being available for retail sale. Thus, opportunism may play a significant role in these incidents. Overall, these experts claim that historically, incidents involving use of biological or toxin agents since 1970 have produced fewer than 100 fatalities, despite the biotechnological revolution.

On the other hand, since the beginning of the 20th century, a number of states have initiated and maintained their own biological weapons programmes. Since World War I, the United States, France, the Soviet Union, Germany, the United Kingdom, Hungary, South Africa, Iraq and Iran, as well as a number of other states which likely still maintain biological weapons, have designed explicitly offensive biological weapons programmes. Within these programmes, especially those of the United States from the end of World War II through to the middle of the Cold War, and correspondingly in the Soviet Union for about two

3 While biological weapons are made from living pathogens, chemical weapons rely on the toxicity of chemicals; toxins are toxic chemical substances produced by living agents. According to Britannica.com, "The term is sometimes restricted to poisons spontaneously produced by living organisms (biotoxins). Besides the poisons produced by such microorganisms as bacteria, dinoflagellates, and algae, there are toxins from fungi (mycotoxins), higher plants (phytotoxins), and animals (zootoxins)." <http://www.britannica.com/EBchecked/topic/601221/toxin >.

decades during the Cold War, it was clearly demonstrated that biological weapons could be effectively used against humans, animals and plants on a variety of different scales, including up to the level of being considered 'weapons of mass destruction' (WMDs). Therefore, there exist two different histories of state-level involvement in the use or misuse of biology, in contrast to non-state use or to misuse.

Finally, some researchers have argued that in the current age of molecular biological research, the distinction between chemical and biological weapons has decreased in significance. Within the international community, this distinction has been reinforced by the existence of two separate charters governing the regulation of these different categories of weapons, namely the Chemical Weapons Convention (CWC) and the BTWC. In fact, some experts have maintained that rather than separate these two categories, they should be forged together in a chemical-biological threat spectrum. Other experts hold that chemical and biological weapons occupy different spaces in military doctrines, and that to place them together may hinder efforts at disarmament. Still, those experts who support this theory point to the general overlap in the BTWC and CWC with regard to toxins use as one of the main reasons for combining chemical and biological threats together. However, given the ambiguities in both the BTWC and CWC related to non-lethal agents, these experts argue that not adopting such a spectrum may lead to a creating a gap in this category rather than an overlap.

At the low-end of this chemical-biological spectrum are the classical chemical agents, such as nerve agents; the spectrum then progresses through to industrial chemicals (chlorine and phosgene), mid-spectrum agents (such as toxins and bioregulators), then to traditional biological agents and finally to genetically-modified biological agents. Such a tiered conceptualisation is advantageous as it adequately shows the complexity and interconnectedness of the combined chemical-biological weapons threat.

Looking back on the history of warfare in the 20th century, with the multiple documented instances of the use of biological weapons in conflicts such as World War I, in China during World War II, the use of Agent Orange in the Vietnam War (which can be considered as much a biological weapon as a chemical weapon), it is interesting then that many commentators have argued that the era of biological weapons lies in the 21st century. Writing in 1989, British biologist Steven Rose, stated his belief that "[t]he outlook for biological weapons is grimly interesting. Weaponeers have only just begun to explore the potential of the biotechnology revolution. It is sobering to realize that far more development lies ahead than behind." [4] In the 20 years since the publication of Commander Rose's paper, the great strides in biological research have emphatically substantiated his claim.

Indeed, so great have been the advances in biological research since the start of the 21st century that the question of their significance has been revised. Biotechnology will be a major technology in the 21st century, if not the most important. According to US molecular biologist Matthew Meselson, the question now is whether or not the advances in the field can be kept to solely beneficial purposes. Professor Meselson writes that "[e]very major technology – metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy – has been extensively exploited, not only for peaceful purposes but also for hostile ones. Must this also happen with biotechnology, certain to be a dominant technology of the twenty-first century?"[5] Professor Meselson believes that the advances in biotechnology will be two-fold; not only will new technologies be created that will facilitate the destruction of life, but also new opportunities will emerge for its manipulation, "including the processes of cognition, development, reproduction, and inheritance. A world

4 Rose, [Commander] Steven. "The Coming Explosion of Silent Weapons," Naval War College Review (Summer 1989), pp. 339-354.

5 Meselson, Matthew. "Averting the Hostile Exploitation of Biotechnology," CBTWC Bulletin (June 2000).

in which these capabilities are widely employed for hostile purposes would be a world in which the very nature of conflict had radically changed. Therein could lie unprecedented opportunities for violence, coercion, repression, or subjugation."[6] Thus, what is ultimately at stake if biotechnological development proceeds unchecked is the possibility of a complete transformation of conflict and warfare.

Having identified exactly what is at stake raises the question of how the threat of biotechnology's 'dark side' is being controlled. Many experts consider the US National Academy's Fink Committee Report to be the first major probe by the scientific community into this issue. Published in 2004, the Fink Report[7] was one of the first major scientific documents to acknowledge the potential dual use of biotechnology and its harmful effects. It also "acknowledged a serious gap in the existing domestic US and international oversight arrangements for dual-use research."[8] It made three recommendations to bridge this gap: (1) to review any experiment that could strengthen or alter pathogens or render vaccines ineffective; (2) to create an International Forum on Biosecurity designed to produce international norms for addressing the dual use issue; and finally (3) to establish a National Advisory Board for Biodefence to educate scientists and policymakers on the dangerous use of biotechnology.[9]

Two years after the publication of the Fink Report, another influential scientific document relating to the dangers of biotechnology was published in 2006. Following the groundwork that had been laid by the Fink Report, the Lemon-Relman Report, entitled Globalization,

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6 *Ibid.*

7 National Academy of Sciences. Biotechnology Research in an Age of Terrorism: Confronting the "Dual Use" Dilemma. Washington, DC: National Academies Press; 2004 Available at: http://books.nap.edu/openbook.php?record_id=10827.

8 Rhodes, Catherine and Dando, Michael, "Options for a Scientific Advisory Panel for the Biological Weapons Convention," in A Web of Prevention: Biological Weapons, Life Sciences and the Governance of Research, edited by Rappert, Brian and McLeish, Caitríona (Earthscan, 2007), p. 117.

9 *Ibid.*, p.118.

Biosecurity and the Future of the Life Sciences,[10] extended the threat spectrum away from the narrow focus on pathogens towards a greater understanding of the entire biological threat spectrum. In addition, it also shifted threat perception away from a focus on biotechnology alone, and sought to understand the simultaneous revolutions that were also taking place in the fields of information technology, nanotechnology and combinatorial chemistry, all of which impacted on the capabilities that would be seen in the future developments in biotechnology. Realistically, given the magnitude of the changes that have occurred in the field of biotechnology, the Lemon-Relman Report stated that it was unable to give a sensible forecast of what would happen even within the narrow time frame of the next two or three years. Instead, it suggested that it would be advisable to monitor the changes by looking at groups of technologies related to common purposes. Attempting to categorise technological changes, the report suggests the following groups :

1. Advances in Technologies with Relevance to Biology
2. Acquisition of Novel Biological or Molecular Diversity
3. Directed Design
4. Understanding and Manipulating Biological Systems, and
5. Production, Delivery and 'Packaging'

Focusing on the last group, Production, Delivery and 'Packaging', is extremely relevant to the 'dark side' of biotechnology, as these advancements are the clearest steps towards weaponisation of biological substances. Within this group, a further break down can be made of its substantial contents into different categories, including microfluids and microfabrication, nanotechnology, aerosol technology, microencapsulation technology, gene therapy technologies and targeting biologically active materials to specific locations in the body. The advances in micro-

10 Committee on Advances in Technology and the Prevention of their Application to Next Generation Biowarfare Threats, National Research Council, and Institute of Medicine, Globalization, Biosecurity, and the Future of the Life Sciences, National Academies Press, 2006 (http://www.nap.edu/catalog/11567.html).

fluids and microfabrication in the past decade have been astounding, as a whole new kind of chemistry has been developed that is now aligning the production of a massive number of new chemicals with the rapid capability to test these products on different biological systems. This group also includes advancements in nebulizers, so that drugs can reach the lungs of patients more readily. However, while the good intentions of the researchers and scientists currently working on these developments are not called into question, at the same time these advances relate directly to the delivery of biological and chemical agents. Thus a large part of the effort in combating the misuse of biotechnology will involve the dissemination of information to researchers and scientists in the life sciences field, to increase awareness of how these advances can potentially be misused.

The risks of biological misuse seem to be clear for the future. In particular, the threat of initiating new biological and chemical offensive weapons programmes looms large. Up to present, traditional biological agents substantiate a low-level threat to security, as they have few characteristics to make them useful as biological weapons. It is therefore conceivable that most traditional defence systems can cope with these agents. Experts theorise that these agents could be genetically modified with enhanced resistance to overcome traditional defences, but once again these modifications have only a limited impact, and only a few manipulations would be effective for a short period of time until defence mechanisms could respond, adjusting to the new threat.

However, analysts say that in the coming decades, as our knowledge of fundamental life processes increases exponentially, offensive biological weapons would no longer be built around a particular agent, but rather would become target-specific, based on what the offensive force would wish to achieve against multiple targets within the living system. Analysts thus conclude that this scenario would lead to a prolonged period of offensive dominance in the framework of an offence-defence

arms race. This scenario would present a grave danger to humanity, and would best be avoided by concerted action in the near future.

As previously stated, there is no single solution capable of completely eradicating all possible hostile use of biotechnology in the future. Some experts have suggested that what is necessary is an integrated web of policies which together will raise the costs of such hostile actions high enough to prevent the misuse of biotechnology. At the minimum, such a protective web would need to include the following elements:

1. Security and Scientific Intelligence
2. Coordinated Export Controls
3. Strong International Arms Control Regimes (with in-depth national implementation)
4. Sensible Chemical-Biological (CB) Defence Programmes, and
5. International Responses to Deviations

All of these policies must be pursued and strengthened at every possible opportunity. Centrally, however, this web of prevention is meant to strengthen the BTWC and the CWC, as well as render criminal those involved in the promotion of the 'dark use' of biotechnology. The two forthcoming reviews of the BTWC and the CWC will be instrumental in building this comprehensive security network. Some experts hope that the 2011 BTWC Review Conference will lead to a consolidation through the imaginative and flexible work of the participants representing the life sciences, national governments and international organisations. It is also hoped that this Conference will succeed in strengthening confidence in compliance or produce a more effective confidence-building mechanism, enhanced capacity of the BTWC and a more effective verification system. Though the CWC is currently in a much stronger state than the BTWC, for the 2013 CWC Review Conference some experts have noted a problem with the current exemption found in Article II.(9) that allows chemical agent development for the peaceful purposes of

"law enforcement, including riot control."[11] Given the developments in neurochemicals, a broad interpretation of this exemption could lead to the development of agents that would erode the entire spirit of the CWC. The importance of the BTWC to the proposed web of prevention will be highlighted in the next section.

B. A Detailed Look at the Biological and Toxin Weapons Convention (BTWC)

The view on bio-threats in the 20th century was rather simple compared to the added complexities brought forth by the many advances made in biotechnological research in the past decade alone. The 20th-century approach focused mainly on state biological weapons programmes and the use or accidental release of such weapons. Towards the end of the century, however, the idea of bioterrorism was introduced, along with the ability of non-state actors to procure such weapons. The BTWC was founded upon this rather limited view of the threat posed by biological weapons.

The international response to this ideational creation of biothreats had actually begun in 1925 with the Geneva Protocol, which prohibited the use of chemical ("asphyxiating, poisonous and other") and biological ("bacteriological methods of warfare") weapons in war, but did not refer to the production, transfer or storage of these agents. A more comprehensive treaty was put in place in 1975 with the entry into force of the 1972 BTWC, prohibiting the development, production, stockpiling, acquisition, retention or transfer of biological weapons. Such an initiative was extended by UN Security Council (UNSC) Resolution

11 Article 2 (9):"Purposes Not Prohibited Under this Convention" means: (a) Industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes; (b) Protective purposes, namely those purposes directly related to protection against toxic chemicals and to protection against chemical weapons; (c) Military purposes not connected with the use of chemical weapons and not dependent on the use of the toxic properties of chemicals as a method of warfare; (d) Law enforcement including domestic riot control purposes."

1540, requiring all states to prevent WMD terrorism, including the use of biological weapons.

Currently, the BTWC includes 163 States Parties, with an additional 13 signatories; 19 States have neither signed nor ratified the treaty. Its main provisions (Articles I and II) are intended to fully prohibit any acquisition or retention of biological or toxic weapons. Article III prohibits the encouragement or assistance to others (both states and non-state actors) in acquiring biological weapons, and Article IV calls for national implementation measures to be put in effect. However, Article V states that the peaceful uses of biological science and technology are to be protected and encouraged.

Thus, while the BTWC has fewer States Parties compared to the Nuclear Non-Proliferation Treaty (NPT: 189) or the CWC (188), it does have a strong advantage in the call for complete prohibition of biological weapons, without exception. By implementing a complete ban for all parties, the BTWC has created a strong global norm against the development and use of biological weapons, which contrasts significantly with the results of the NPT. Some experts believe that no government today would claim to reserve the right to keep biological weapons as a part of their strategic defence deterrent, a significant change from the 1950s and 1960s, when biological weapons formed simply another part of a state's overall WMD arsenal. Today, if biological weapons programmes still exist, they are conducted in secret, and governments are fully aware that detection would lead to massive international denunciation.

One major disadvantage of the BTWC, however, is that there exists today no organisation to serve as an implementing body for its provisions. In this, the BTWC departs from other international treaties. For example, the NPT is administered by the International Atomic Energy Agency (IAEA). Chemical weapons are similarly governed by the CWC and administered by the Organization for the Prohibition of Chemical Weapons (OPCW). The Comprehensive Test Ban Treaty (CTBT),

once in force, will be verified by the Comprehensive Test Ban Treaty Organisation (CTBTO). For biological weapons, the BTWC States Parties have created an Implementation Support Unit (ISU) within the UN Office for Disarmament Affairs in 2006, but it is a small office that is not capable of handling large-scale implementation oversight. As a result, the BTWC has no verification mechanism in place, as is the case with the OPCW. Finally, since the BTWC was written at a time when the main concerns were state-based biological weapons programmes, its provisions are inadequate to combat the procurement and use of biological weapons by non-state actors.

The changes ushered in with the 21st century have made necessary a revision of the BTWC's objectives and an expansion of its areas of concern. The terrorist attacks on 11 September 2001 brought awareness of the new significance of the threat of bioterrorism in the future. The likelihood of such an event had increased with the rapid growth of biotechnology. An example of the scale of this growth is to be seen in the sheer number of facilities which could be involved in the process of developing biological weapons. It is estimated that over 50,000 such facilities exist around the world today. By contrast, the IAEA estimates that there are today only 1,000 facilities which could produce components for nuclear weapons, and the OPCW estimates that the corresponding figure for chemical weapons is 5,000. These comparison figures demonstrate not only the massive growth of biotechnology in the first decade of the 21st century, but also the difficult challenges in striving to regulate or to verify that these research facilities are not used as a threat to humans or to the Earth's environment.

The 21st century has also seen a greater acknowledgement of the interconnectedness of all biological risks. The growth of biotechnology has reduced costs and has made biological research more easily accessible to the amateur level. This greater involvement on the individual, non-professional level thus can have unintended consequences relating

to accidents or misuse. As a result, the fragmented nature of biological research means that not only are international frameworks such as the BTWC unable to provide any sort of comprehensive oversight, but the scientific community has found its own self-regulatory mechanisms also to be ineffective.

The spectrum of biological risks in the 21st century presents a variety of inter-related eventualities. The less intentional include occurrences such as natural disease outbreaks, unintended consequences, accidents and negligence. At the level of intentional misuse, degrees of risk increase towards negligence, vandalism and sabotage, through to the deliberate use of biological weapons. However, other experts have noted that biotechnology-related concerns go beyond armaments; for example, abusive use of the knowledge of the human genome could lead to new uses of conventional weapons. Some experts argue that, when applied to the changing nature of warfare, DNA technologies and forensic genetics are now being used to take samples from individuals in war zones without their consent in order to gather intelligence that could lead to further investigation and interrogation of targeted groups. These potential human rights violations demonstrate the added complexity of the unpredictable new uses of biotechnology in different areas, and for the need for appropriate international tools to monitor and control any inappropriate or illegal usage.

Nevertheless, proponents of this spectrum have stated its utility: it demonstrates that health experts and law enforcement agencies must cooperate to successfully meet these challenges. Indeed, as the UN and its partner organisations have worked towards making biosecurity a priority, it is crucial that the various organisations concerned by the spectrum are interlinked and communicate with one another. As a result of this interconnected approach, the focus on the BTWC has shifted away from the traditional 20th-century role of an implementing organisation with a verification protocol towards the promotion of greater

national implementation, with each state coordinating its own national agencies based on the new biotechnological environment. The BTWC has its own annual work programme of meetings of States Parties and experts dealing with specific topics on issues that cover the whole spectrum of risk. These include the following:

1. National Implementation (2007)
2. Regional Activities (2007)
3. Biosafety and Biosecurity (2008)
4. Oversight, Education and Outreach (2008)
5. Capacity Building for Disease (2009), and
6. Response to Use or Threat of Use (2010)

The BTWC has brought together a range of different actors in a network approach, including professionals from such diverse fields as health, industry, agriculture and science. This activity is coordinated by the Implementation Support Unit (ISU), which has renewed the focus on confidence-building measures and is striving to make the BTWC universal. The ISU's network approach has now linked with a number of other security-oriented organisations, such as INTERPOL, the 1540 Council and the World Health Organization (WHO). In addition, the review meetings organised by the ISU lead to the creation of a number of non-binding common understandings that help facilitate implementation (See Appendix 1 for a reprint of the 2008 Common Understandings.).

The concerns shared between biosecurity and general public health seem to be well understood by the upper echelon of the international community. Indeed, much of the work of the BTWC has been legitimised by the actions of former UN Secretary-General Kofi Annan and current Secretary-General Ban Ki-moon. Speaking in 2006, Secretary-General Annan stated that greater public health capacities would be one way to strengthen safeguards against bioterrorism, and that this relationship was mutually reinforcing. At the same time, Mr Annan also recognised the symbiotic relationship between increased laboratory

safety, and increased technology and development. Contextualising the battle against bioterrorism, Mr Annan also stated that fighting bioterrorism was more akin to measures to control cybercrime than those in place to control nuclear proliferation.[12] Current Secretary-General Ban has continued the work of his predecessor, continually highlighting the new nature of the biological threat spectrum. In 2008, he also called on all levels of society connected to the spectrum to join together in "a cohesive, coordinated network of activities and resources. Such a network will help to ensure that biological science and technology can be safely and securely developed for the benefit of all."[13]

The 21st century has seen radical changes in the field of biotechnology that have in turn transformed the substantive nature of how the biological threat is perceived. The move away from state programmes and verification measures towards a more coordinated network approach has begun to take shape both at the national level (as exemplified in the publication of the Fink Committee Report and the Lemon-Relman Report), and at the international level with the work of the BTWC, the UN and its related organisations. The aim of this network is to ensure that biotechnology proceeds in an open fashion that can work towards mutual benefit, while managing the risks of possible misuse. The following sections outline different strategies for more effective regulation of this careful balance between risk management and open development.

12 Annan, Kofi, "Uniting Against Terrorism: Recommendations for a Global Counter-Terrorism Strategy," Report of the Secretary-General. A/60/825. New York: United Nations, April 2006 (available at: http://www.un.org/unitingagainstterrorism/contents.htm).

13 Ban Ki-moon, "Secretary-General's message to meeting of States parties of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction," 1 December 2008 (available at: http://www.un.org/News/Press/docs/2008/sgsm11971.doc.htm).

Options for Biosafety and Biosecurity Governance[14]

The aforementioned expert opinions on the unpredictable explosion of biotechnology research already conducted and to be further conducted in the 21st century have substantiated the need to build regulatory mechanisms in this field. The question then arises as to what shape such mechanisms will take. Regulation is possible on a number of different levels – individual (or within the scientific community itself), state and international levels. Many experts, however, have pleaded that the scientific community is not sufficiently aware of the dual-use phenomenon of biological research. For example, one expert reported that in his conversations with twenty European synthetic biologists over the past few years, not a single one had heard of the Lemon-Relman Report and its findings. Moreover, even though such awareness is growing, many life scientists refuse to believe that their research could have unintended consequences in different areas. Given the lack of understanding observed among life scientists of the dangers of biotechnology, education on this issue is crucial if the risks of the misuse of biotechnology are to be reduced.

14 On this whole issue, see a previous GCSP publication: Al-Rodhan, Nayef; Nazaruk, Lyubov; Finaud, Marc; Mackby, Jenifer. Global Biosecurity – Towards a New Governance Paradigm, Slatkine, Geneva, 2008 (http://www.gcsp.ch/e/publications/Globalisation/Publications/Books/Dec07-Jan08/Global-bio.htm).

Building upon this premise, then, these experts argue that not only must self-regulation within the scientific community be strengthened through greater awareness-building amongst life scientists themselves on the dangers of the dual-use of biotechnology, but that a network of regulatory mechanisms from outside the science field must be constructed at the same time. When discussing possible structures to oversee that biotechnology is used solely for the benefit of mankind, thereby ensuring that any 'dark use' consequences are held in check, it is tempting to use the word 'regulation' to describe this process. However, given the complicated relationship between science and regulatory bodies, it is perhaps more advisable to think of these structures in terms of 'governance', which implies more inclusive, engaging and democratic processes. And indeed, most experts agree that some form of governance is absolutely crucial to prevent biotechnological developments that could be potentially beneficial to states or non-state actors from being misused in the promotion of any agendas against humans, plants or animals.

Given the fragmented and decentralised nature of the biotechnology field, any sort of governance programme will require clear goals and targets if it is to work. These must be amenable to change in keeping with the rapid developments in the field. To maximise preventive measures, they also need to be coordinated between different stakeholders who can detect possible opportunities for misuse at various levels. However, these governance structures cannot be top-down oriented. Rather, they must mesh with the culture of openness and freedom inherent in the scientific community and at the same time convey knowledge of shared responsibility and any possible negative implications of research to those life scientists who wish to undertake projects that may be deemed unsuitable.

When discussing the goals and targets for biosafety and biosecurity regulation, it is important to remember that these two concepts, though

related, are distinct from one another; biosafety does not equal biosecurity. One possible example of distinguishing the two concepts was made by the German Delegation to the BTWC in October 2006, when it stated that "[w]hile a biosafety risk classification system is based on the inherent capability of micro-organisms to cause disease, of greater or lesser severity, in humans, animals and plants, a biosecurity risk classification system is founded on the potential of a micro-organism or toxin to be used as a weapon." [15] This understanding shows both the dual-use of biotechnology from a different perspective, while at the same time reiterates that biosecurity is far more extensive in scope than merely a focus on bioterrorism.

The targets of proposed governance structures are diverse. Most life scientists are engaged in biotechnology research, and quite a few government regulations exist to deal with research from a biosafety perspective. However, this is far less the case as regards biosecurity. Moreover, a crucial point regarding the BTWC is that it begins with prohibitions of the production of biological weapons, but does not contain any stipulations concerning research. Other targeted phases for regulation include development, production and the use of biological agents, both in a contained setting and its release into the environment. Each of these areas already has certain biosafety guidelines, but again, the picture is less clear from a biosecurity perspective.

A. Biosafety Governance at the National Level

On the national level, there exist different mechanisms that further complement the aims and targets of regulation. It is useful to look at the example of the United States (US) and the growth of biosafety governance measures there to see how national regulatory mechanisms

15 Speech by Germany, on behalf of the European Union, 20 October 2006, BTWC/CONF.VI/WP.2 (available at: www.opbw.org).

can evolve and adapt over time. After the Asilomar Conference on Recombinant DNA in 1975, where biotechnology professionals drew up voluntary guidelines regulating the safety measures for future experiments, developments in biosafety in the US have proceeded in three stages. The first stage was a continuation of the self-regulatory initiative seen at Asilomar. However this was subsequently judged insufficient for implementation of adequate biosafety measures within the life sciences community at large. These regulatory attempts were then supplemented by independent federal scientific oversight by the National Institutes of Health, its Recombinant Advisory Committee and a set of guidelines.

Still, within the US political sphere, there remained a sense of disquiet over this range of regulatory mechanisms. This then led to the development of a coordinated framework to regulate biotechnology-based products. This emphasis on products demonstrates one approach to regulation within the biotechnology sector. Another approach, currently adopted by the European Union (EU), is to base regulation on biotechnological processes. These different approaches illustrate how regulatory mechanisms may be constructed depending on their primary premise or focus. Such diverse approaches at the national level also illustrate the numerous additional complexities that can come into play in attempts to bring about a cohesive and effective international regulatory regime.

In addition to the different levels of regulation, developments in the various fields of biotechnological research add further complexity to any proposed regulatory regime. The case of synthetic biology, one of the cutting-edge fields in the life sciences today, provides an interesting example of both the speed of change within this field, and ability required to comprehensively alter its entire working paradigm. Experts who promote this new field predict that synthetic biology will change the essence of biology from a descriptive science to a predictive science. Until now, biology has largely been a field devoted to understanding, characterising and cataloguing biological systems and organisms. A move

to a predictive science means that once the genetic coding of a certain function is known, it can be inserted into a specific organism that will then express this function. The scale of synthetic biology potentialities goes beyond the traditional genetic engineering approach. While genetic engineering functions on a trial-and-error basis and a one-by-one scale, synthetic biology looks towards a much broader scale, functioning more on engineering principles and controlling many more variables within a single organism. Thus, the aim of synthetic biology is to write and synthesise DNA as opposed to simply reading and analysing it. It seeks to control the design and construction of new biological systems.

Such groundbreaking change would quickly render any static regulatory mechanism obsolete. However, experts claim that synthetic biologists are more aware of the potential dual-use within their field, and different suggestions have been made to enhance biosecurity and biosafety. One of the earliest proposals, in 2004, was made by Dr George Church, in "A Synthetic Biohazard Non-proliferation Proposal."[16] Dr Church recommended that DNA and oligonucleotide orders used by synthetic biologists be screened for similarity to select agents. In addition, it was recommended that certain instruments and reagents used in the synthesis of larger DNA blocks should be licensed.

While the latter recommendation has not been followed up on in subsequent reports, the screening recommendation has been repeated by different experts since 2004. With the growth, over the past five years, of DNA synthesis companies which can synthesise genome-length DNA strands at a reasonable cost, calls have come forward for regulations to screen incoming orders. This recommendation was seen in the resolutions of the Synthetic Biology 2.0 Conference in May 2006, which supported the "development of improved software tools that can be used to check DNA synthesis orders for DNA sequences encoding hazardous

16 Available at: www.marmotpower.com/Biodocs/Church.pdf.

biological systems" and the "adoption of best-practice sequence checking technology, including customer and order validation, by all commercial DNA synthesis companies." [17]

A proposal put forward in 2007 by the International Consortium for Polynucleotide Synthesis (ICPS) has so far contained the most ambitious recommendations for DNA screening. The scientists who contributed to this article recommended a "tiered DNA synthesis order screening process" which would place both DNA synthesis companies and industry associations at the centre of a larger governance structure. Unlike other life sciences practitioners and groups, the ICPS is not adverse to government involvement in the process, and their regulatory proposals are based on mutually-acceptable guidelines involving government oversight.[18] This proposal restates the themes seen in US national regulations of biotechnology in general, wherein the initiative begins at the level of life scientists and then grows to a partnership with the government. Some experts have argued that this may be because the biotechnology industry would like to see legal certainties put in place through political channels in order to be more commercially successful. This may be due to the fact that government involvement may confer a greater sense of legitimacy for the industry than self-regulation alone. Still, it should be noted that for the time being, these proposals largely deal more along the lines of biosafety than biosecurity.

On the other hand, a proposal made by the Industry Association of Synthetic Biology (IASB), which primarily represents German companies, demonstrates what some experts hope to be a shift away from strict technical solutions towards ensuring that DNA synthesis orders are placed solely for legitimate and beneficial purposes. In 2008, the IASB issued recommendations on the development of advanced

17 Declaration of the Second International Meeting on Synthetic Biology, 19-20 May 2006, http://syntheticbiology.org/SB2Declaration.html.

18 Hans Bügl et al, "DNA Synthesis and Biological Security," Nature Biotechnology, 25:6 (June 2007), pp. 627-629.

screening software for DNA orders, and is now working on a code of conduct for DNA-synthesis companies that goes beyond technical screening issues alone.[19]

The previous examples of governance in biotechnology demonstrate that although first steps towards building regulatory mechanisms have been made in different industries, they have done so largely in an unstructured and unsystematic way. While there are no cure-all solutions for developing regulation, more structured approaches could lead closer to the coordinated web of protection that many experts believe is needed. To that end, heuristic devices could be useful in synthesising information on different regulatory mechanisms that have sprung up in different areas of the biotechnology industry. One such device is the "5P-Governance Matrix" developed by Dr Alexander Kelle (reproduced in Appendix II). The matrix proposes five policy intervention points where governance and regulatory oversight may be introduced: the principal investigator; the project that is to be researched and/or developed; the premises where the activity is taking place; the provider of genetic material; and the purchaser of the material. The left side of the matrix adds a number of different biosecurity measures found in the literature that can be applied to these policy intervention points. These include: awareness raising; education and training; formal and informal guidelines; codes of conduct; regulation; national laws and international treaties.

The '5-P matrix' thus seeks to construct an overview that has so far not been conducted into the existing disconnected regulatory mechanisms, to assess what is already available, where the gaps are and where attention should be devoted to building more comprehensive mechanisms. It is designed to organise and classify existing policies, but does not give

19 IASB, "IASB Develops Security Measures for Use of Synthetic Biology", 3 Apr. 2008 (http://www.ia-sb.eu/go/synthetic-biology/synthetic-biology/biosafety-biosecurity/security-of-synthetic-biology/iasb-develops-security-measures-for-use-of-synthetic-biology/).

insight to the substantive nature of the policies themselves. However, it does contribute to synthesise existing policies, and could be useful as a first step in developing more comprehensive governance structures.

B. International Biosecurity Governance Strategies

As evidenced in the last section, some experts believe that self- and national regulatory systems tend to focus more on biosafety than on promoting biosecurity. Perhaps more could be done internationally to build working integrated systems within this realm. Again, much of what is recommended is based largely on the context of what are considered to be the main threats and the main target of involvement. There also exists a range of other specific issues that may prove challenging to integrate into a comprehensive governance network.

Biosecurity differs from biosafety in the significant ways described above. Some experts, therefore, remain wary of the feasibility of applying similar biosafety governance mechanisms when building governance mechanisms for biosecurity. For example, these experts argue that biosafety measures lend themselves better to risk-benefit analysis when judging research based upon its possible positive and negative contributions to the field. However, these experts hold that such a policy in terms of biosecurity could prove to be problematic. These solutions could take the form of simple basic checks when submitting articles for publication in major journals. Some journals have questionnaires asking submitting authors whether their work could potentially compromise biosecurity standards. However, no article has ever been refused on biosecurity grounds, which leads one to wonder whether or not these measures, though not very costly, actually produce effective results. This seems to reflect the general tendency within the life sciences to believe that the benefits of such research far outweigh any sort of risk of misuse, a point many experts find very disconcerting. If such a prevalent

mindset exists among life science practitioners, as many experts argue is the case, then risk-benefit analysis cannot be the basis of a strong biosecurity governance regime.

It has been acknowledged by most experts that the logical point of entry within the disarmament and arms control community's perspective on biological weapon production and proliferation is to focus on the weapons themselves, which has been the goal of the BTWC since its inception in 1972. Yet there are other possible points of entry to which the BTWC could contribute. One of these could be disease prevention, irrespective of how it originates. According to WHO statistics, some 50 per cent of mortality in developing countries is attributed to infectious diseases, compared to 25 per cent worldwide. This amounts to between 15 and 16 million people per year who die of infectious diseases alone, an enormous figure and, according to many experts, a threat much more salient than the production and stockpiling of biological weapons.

Other possible points of entry exist as well. For one, a look at how biology and biotechnology can contribute to societal advancement in the form of economic development, health security, food security and to help solve other challenges. Another could be to focus on environmental security, and the impact of accidental or purposeful introduction of organisms in new biotopes or of modified organisms. Overall, in the context of current international biosecurity architecture, it is important to understand how the BTWC relates to these alternative points of entry, and what it can do to address these different issues.

Currently, the BTWC largely focuses upon the prevention of deliberate disease introduction, regulated by the Geneva Protocol and a number of Review Conferences. Furthermore, some experts have questioned the relevancy of the bargain framed within the BTWC between Article III (prohibiting provision of assistance in developing biological weapons) and Article X (which promotes the free use of biotechnology for peaceful purposes). On a world scale, the natural diffusion of

biotechnology through global trade and development is already under way, and it is unclear what these articles will contribute to the future of the Convention, considering that there are now multiple sources to biotechnology. Indeed, even some developing countries have become net exporters of biotechnology. For these reasons, experts argue that linking the free and peaceful use of biotechnology to prohibitions on biological weapons may become anachronistic in the future for regulating biotechnological transfers between states.

Hence, the question to consider regarding the role of the BTWC in the global biotechnology governance regime is how inclusive and effective is the organisation in addressing such issues? Given the limited nature of the BTWC as presented in the first section, many experts have suggested to involve other organisations in building such a regime. These would include organisations from a number of different categories:

1. The category of weapons control – in addition to the multilateral agreements of the Geneva Protocol, the BTWC and the CWC – would include:

a. Proliferation prevention arrangements such as the Australia Group, the Proliferation Security Initiative (PSI) and the G-8 Global Partnership;

b. UN agencies and International Humanitarian Law organisations such as the International Committee of the Red Cross (ICRC).

2. The second category, disease prevention, could include involvement by:

a. The WHO,

b. The Food and Agriculture Organization (FAO), and

c. The Organization for Animal Health (OIE).

3. The third category, crime and terrorism, could include:

a. The architecture put in place by UNSC resolutions (such as the 1540 Committee),

b. INTERPOL and

c. Other international intelligence agencies collaborating with law enforcement.

4. The final category of international transfers could include involvement by:

a. The World Trade Organization (WTO) and

b. World Customs Organization (WCO).

While various niches certainly exist for bringing together different international organisations with specific fields of expertise, there remain a number of different questions as to what shape any international governance structure would take in the future.

First, most experts agree that there is at this moment little clarity about the specific goals of biogovernance. This is due to the previously-mentioned complex set of factors that must be taken into consideration, the competing institutional imperatives and the presence of commercial interests, as well as competing levels of policy action.

In addition, new security actors such as terrorist and criminal entities further complicate the picture. Some experts also wonder whether it is possible to reconcile security and economic imperatives, and note that, in some areas, transparency and access to information are being compromised at the behest of biological laboratories striving to conduct their affairs in secret to better their own economic prospects.

On the other hand, with a number of differing security, development and economic priorities, some experts question how much states are willing to contribute in terms of resources in order to develop comprehensive international biosecurity mechanisms.

In the end, as the BTWC remains the guardian of the main tangible international advances towards an agreement on governance mechanisms, some experts believe that it remains at the behest of the BTWC to demonstrate how effective it shall be in addressing these new concerns, and how it will interact with international partners in developing more comprehensive structures for biosecurity and biosafety governance.

Two Proposals for International Governance Mechanisms

Within the field of biotechnology governance, some experts have begun to develop comprehensive governance structures that they feel can complement and enhance the existing international biotechnology governance architecture. These additional mechanisms, they argue, address different gaps that have not been sufficiently covered by the BTWC and other international governance structures relating to this fast-developing field.

These two proposed structures are quite distinct in their focus and operation. However, they are not mutually exclusive but rather complement each other.

The first, "DNA for Peace",[20] seeks to balance biodevelopment and biosecurity in order to redress what some experts perceive to be an inordinate amount of attention paid to the dangers of the misuse of biotechnology, and to build up the genuine excitement felt in many parts of the developing world towards using the advantages of biotechnology to assist their own state economic development.

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20 Singer, Peter A. DNA for Peace: Balancing Biosciences for Development and for Security, Stanford University, 30 May 2008 (available at: www.iis-db.stanford.edu/evnts/4891/DNA_for_Peace_presentation.pdf).

The other proposal, to establish a structure that mimics the Intergovernmental Panel on Climate Change (IPCC) for biotechnology, would be primarily to organise a scientific body of experts who would give their opinions on the threats of biotechnology to safety and security in an impartial forum that could be peer-reviewed and open to public knowledge, with the additional advantage of having the prestige and authority of the UN behind it to give it a pre-eminent place in the biotechnology governance regime.

A. DNA for Peace: Balancing Bio-development and Biosecurity

All experts agree that advances in the life sciences can have great benefits in the fields of global health and development. Where they differ is the extent to which these benefits, which can also be referred to as 'biodevelopment', should be balanced with the real concerns of biosecurity. In addressing this balance, the experts that have proposed the DNA for Peace initiative have sought to emphasise the benefits of biotechnology to the developing world, and to link these benefits to any future biosecurity international governance model.

The DNA for Peace model was designed along the lines of the 'Atoms for Peace' idea envisioned by former US President Dwight D. Eisenhower. In a speech made in December 1953, President Eisenhower stated his view on the responsibilities of the newly formed IAEA. In his opinion, this organisation's "more important responsibility… would be to devise methods whereby this fissionable material would be allocated to serve the peaceful pursuits of mankind. Experts would be mobilised to apply atomic energy to the needs of agriculture, medicine and other peaceful activities. A special purpose would be to provide abundant electrical

energy in the power-starved areas of the world."[21] President Eisenhower believed that the IAEA could be a positive force in spreading the benefits of nuclear power around the world to advance peaceful purposes.

Such an idea was later enshrined in the "grand bargain" of the NPT, signed in 1968. The three articles provided for: non-proliferation of nuclear weapons to those states that did not possess them; a commitment to disarmament for nuclear states; and the promotion of access to nuclear energy for peaceful purposes for all states. A project like DNA for peace, applied to biotechnology, could share a number of elements with the NPT and Atoms for Peace ideas. However, the field of biotechnology is distinct from nuclear energy in a number of different ways, which must thus be reflected in any future global governance architecture:

1. Firstly, nuclear energy is capital intensive, and requires a significant initial investment in order to begin any project.
2. Secondly, its governance is centralised, usually around state regulatory mechanisms.
3. Furthermore, its method of use and operation, and especially its weaponisation, was born classified, and this culture of secrecy has largely persisted to this day.
4. Finally, its international use is governed quite comprehensively by the IAEA, which combines numerous verification structures to ensure and develop peaceful uses.

By contrast, the mobility and dispersed nature of biotechnology has been already discussed. Its accessibility and broad appeal have thus complicated any notion to establish a body like the IAEA for biotechnological governance. As a result, there is no such equivalent institution at

21 Dwight D. Eisenhower, "' Atoms for Peace Address Before the General Assembly of the United Nations on Peaceful Uses of Atomic Energy, New York City, December 8th, 1953," Eisenhower Presidential Archives, http://www.eisenhower.archives.gov/all_about_ike/Speeches/Atoms_for_Peace.pdf.

the international level which comprehensively relates to the governance of both the positive and negative uses of biotechnology.

Experts believe in the possibilities of biotechnology in improving healthcare and economic development in the developing world. For example, breakthroughs in biotechnology could help redress the life expectancy gap between developing and industrialised nations. Currently, life expectancy in Botswana, a relatively prosperous developing nation, is 33 years. By contrast, life expectancy in Canada is 80 years overall, and 83-84 years for women. The gap is enormous, and poses an ethical challenge for humanity. Yet biotechnology can help contribute to redress this imbalance. Some experts believe that there exist a number of different innovations that will be of great significance to developing countries in the near future. Of these, the most important would be:

1. Molecular diagnostics
2. Recombinant vaccines
3. Drug and vaccine delivery systems
4. Bioremediation
5. Sequencing pathogen genomes
6. Female-controlled sexually transmitted infection (STI) protection
7. Bioinformatics
8. Enriched genetically modified (GM) crops,
9. Recombinant drugs, and
10. Combinatorial chemistry [22]

Together, experts argue that developments in these fields can help to solve many of the challenges in global health for the developing world, including: childhood vaccines; new vaccines; insect control; improved nutrition; improved drug treatment of infectious disease; curing latent

22 Elizabeth Dowdeswell, Peter A. Singer and Abdallah Daar, "Increasing Human Security Through Biotechnology," International Journal of Biotechnology, vol 8 nos 1-2 (2006), pp. 119-131.

and chronic infections; and measuring disease and health status accurately and economically in developing countries.[23]

In response to these challenges, there have been numerous examples of practical, positive uses of biotechnology in the developing world. Cuba provides one example of a country that has effectively been using biotechnology. Today, it is the only country that has developed a vaccine for Meningitis B, which has effectively eliminated the disease in Cuba since its introduction in the mid-1980s. In addition, private initiatives in developing countries have worked to develop low-cost vaccines to help make them affordable. One such example of this is Shanta Biotechnics in India, which developed a low-cost Hepatitis B vaccine 23 years after its introduction in industrialised nations. This was largely due to cost, and Shanta was able to lower the vaccine's market price from USD15 to 0.50(cents), and now supplies 40 per cent of the United Nation's Children's Fund's (UNICEF) Hepatitis B vaccines worldwide.[24]

Other examples of developing world biotechnological initiatives abound. In China, Shanghai United Cell Biotech has created OraVacs, a novel oral recombinant cholera vaccine, one of only two oral cholera vaccines available worldwide.[25] In Tanzania, A to Z Textile Mills has become the largest insecticide-treated bednet manufacturer in Africa, creating thousands of local jobs. The significance of biotechnology for Africa, however, goes beyond meeting its health challenges; it is also seen by many leaders as the key to economic growth. This has been expressed by President Paul Kagame of Rwanda, who has stated that "[w]e in Africa must either begin to build up our scientific and techno-

23 Varmus, H. et al, "Public Health: Grand Challenges in Global Health," Science vol. 302 no. 5644 (17 Oct. 2003), pp. 398-399.

24 Frew, Sarah E. et al, "India's Health Biotech Sector at a Crossroads," Nature Biotechnology vol. 25 no. 4 (April 2007), pp. 403-417.

25 Frew, Sarah E. et al, "Chinese Health Biotech and the Billion-Patient Market," Nature Biotechnology vol. 26 no. 1 (January 2008) pp. 37-53.

logical training capabilities or remain an impoverished appendage to the global economy." [26]

Not only Rwanda has realised the power of biotechnological development in furthering its economic development; experts have argued that every African country has given priority to science and technology.. At the regional level, the African Union (AU) has initiated its own High-Level Panel on Modern Biotechnology, which has "[p]rovided a blueprint for harnessing biotechnology in agriculture, health, industry, and the environment to accelerate development in Africa."[27] Out of this Expert Panel came a 20-year plan on how to best develop African biotechnology, identifying certain priorities for development:

1. Standard setting and best practices for biosafety
2. Building capacity for biodevelopment and biosecurity in developing countries
3. Raising awareness of these issues
4. Training and exercises
5. Conducting gap analysis after studying and comparing current biosecurity regimes
6. Developing risk evaluation methods and standards
7. Setting an agenda and priorities for studies in biodevelopment and biosecurity
8. Evaluating potential solutions
9. Implementing research solutions, and
10. Designing an authoritative process to execute these issues

Thus, the benefits of biotechnology research to developing countries are numerous, and should be balanced with the aforementioned risks of biotechnology misuse. One idea put forth by some experts has been

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26 Singer Peter A. and Daar, Abdallah S. "Commercializing African Health Research: Building Life Science Convergence Platforms," Global Forum Update on Research for Health, vol 5, http://www.who.int/phi/MRC.pdf.

27 Singh JA and Daar, AS. "The 20-year African Biotech Plan," Nature Biotechnology vol 26 no 3 (4 January 2008), pp. 272-274.

to link biotechnology and human security together, in order to emphasise the importance of balancing both the 'bright' and 'dark' sides of the issue. Different definitions of human security exist; one expanded version would be "to safeguard and expand people's vital freedoms and human dignity, shielding them from threats and empowering them to take charge of their own lives."[28]

However, the example of the development of the Kampala Compact[29] in 2005 demonstrates the sensitivity of addressing the negative aspects of biotechnology. As a whole, the document shed light on the need to balance both the positive and negative aspects of biotechnology. Briefly, the document stated that "[a]ddressing biological weapons concerns inappropriately could undermine development of biological science and technology with catastrophic effects. Developing bio-science but failing to address biological weapons concerns could lead to catastrophe and undermine confidence in science." [30] The document also identified synergistic opportunities between the biodevelopment and biosecurity agendas, and called for a networked governance system that would enhance the 'bright side' while diminishing the likelihood of the emergence of the 'dark side'. [31]

While the Kampala Compact seems on the surface to be a balanced document, acknowledging the dual use of biotechnology, it was not well-received by the Ugandan press, which largely emphasised the importance of biosecurity. Headlines seen included "African Science Policy 'Must Address Bio-Terror Threat'" and "Biological Terrorism a Lethal Possibility." This illustrated the danger of outside sources distorting the goals and messages of dual use, as well as the ease of

28 Dowdeswell, Elizabeth et al. "Realising the Promise of Genomics: Exploring Governance," International Journal of Biotechnology, Vol. 8 Nos. 1&2 (2006).

29 Kampala Compact: The Global Bargain for Biosecurity and Bioscience, 1 Oct. 2005, available at: www.law.depaul.edu/centers_institutes/iwcc/pdf/kampala_compact_oct05.pdf.

30 *Ibid*.

31 *Ibid*.

Western concepts of biosecurity to be imposed on audiences in the Global South. Finally, it also demonstrated that the concept of 'bargain' was not adequate to properly refer to the actual balance between the two sides of biotechnology.

To bring this balance closer to reality in the international governance architecture, some experts have proposed two linked concepts – a global biotechnology initiative, and a network mechanism to link the different fields of specialisation together. The global initiative would work towards the following goals:

1. Promote biotechnology as a public good
2. Encourage equitable participation
3. Strengthen capacity in biotechnology
4. Prioritise needs and foresight activities
5. Design financing alternatives
6. Examine intellectual property rights and other ethical and legal considerations
7. Inspire appropriate regulation [32]

Furthermore, the initiative was designed to complement existing networks due to its focus on both positive and negative aspects of biotechnology. It would therefore work to create a 'network of networks', much like the initiatives of the BTWC. However, its main point of departure, which largely differs from notions of biotechnology in the industrialised world, is that investment in biodevelopment logically precedes any notion of building protection against the misuse of biotechnology.

In 2006, the experts who espoused this global initiative combined its ideas into a more comprehensive package, entitled 'DNA for Peace.' Much like the preceding initiative, this endeavour restated the primacy of the promotion of biotechnology for the benefit of human development, and the investment in positive applications of biological sciences

32 Dowdeswell, op. cit. p. 123.

as a means in and of itself of protecting against its own misuse. Overall, the initiative restated the network package, and in addition recommended that the G-8 begin to identify an appropriate host organisation for launching to programme. As stated above, it appears that the UN Secretary-General's Office has taken the lead in organising the international platform for biodevelopment and biosecurity. Much will depend on what this prioritisation of biotechnology yields in the near future.

In conclusion, experts believe that certain elements are needed to carry the initiative forward to becoming actual policy:

1. First, a global champion must be at the nexus of development promotion and biotechnological security. The Office of the UN Secretary-General was identified as the ideal candidate.
2. In addition, a common vision needs to be adopted for the promotion of human security through the life sciences, combined with sustained engagement amongst the various initiatives and networks on the international scene, or the evolution of networked governance.
3. Finally, a suitable model must be found to effectively fund the initiative and make it accessible to all developing countries.

B. Establishing an IPCC-like Body for Biotechnology

The belief of many experts that self-regulation within the biotechnology community is at present inadequate to secure the field against negative uses has led some to propose the establishment of a non-partisan research forum modeled on the IPCC. The aim of the forum would be to bring together the scientific research in this field, currently unstructured, to better ascertain the real threats, dangers and opportunities to be addressed for effective biosafety and biosecurity. Most experts believe that the difficulty in initiating the construction of the aforementioned 'web of protection' is largely due to the fact that there does not as yet exist a scientific consensus on the risks of biotechnology. A few experts

have gone so far as to criticise the scientific community for espousing self-regulation as an ideological belief, one that does not seem adequate to solve the challenges posed by the 'dark side' of biotechnology, which many biologists themselves believe to be an existential threat to global security. Such experts feel that self-regulation is an untenable policy, one which will be abandoned by an outraged public and governments at the first dramatic incident, and which shall portray the scientific community in a negative light once a first incident occurs.

Experts maintain that if the scientific community is to accept external governance mechanisms, scientists must be informed of the potential dangers of biotechnology. Investigating possible models to aid in developing scientific opinion on the issue, academic research has shown that the minimum requirements for building cooperation are trust and information. Currently, both of these elements are sorely lacking at different levels in the field of biotechnology. It is believed that not only do life sciences practitioners possess insufficient information on the dual use of biotechnology, but the public-at-large has a largely negative perception of the biotechnology field. Hence, any educational initiative will need to take place on a grand scale, for the benefit of scientists, policymakers and the general public. It will need to employ the strengths of science, namely objectivity and peer review, to further develop among scientists awareness of the possible consequences of unchecked biotechnological development.

The IPCC was suggested as a potential role model for this new education initiative, for a number of reasons. Formed in the late-1980s, the IPCC was confronted with a lack of both scientific and political consensus on the issue of climate change. To create such a consensus for climate change assessment, the IPCC offered an open, inter-governmental panel, which meant that once governments signed off on the findings of the Panel's reports, they were bound to the results and could not repudiate them afterwards. Uniting both the scientific and political

communities to build consensus on climate change issues, the IPCC included a rigorous analytical process with stringent peer-review guidelines. Experts put forth different ways in which an IPCC-like body for biotechnology could respond to current lack of trust and information across the board, due to the different incentives for each industry in the biotechnology field. While some industries would fear that their work would be deemed to pose an elevated risk to global security, others could find that their work would be legitimised by the Panel's findings. For example, biotechnology companies working in the production of genetically-modified organisms (GMOs) would stand to benefit in the eyes of the public if the Panel were to find that the threats posed to the environment by GMO products were overstated. Experts believe that incorporating a wide range of biotechnology fields would allow for many actors to have a stake in the outcomes of the Panel.

Proponents of such a Panel claim it would be able to make assessments for possible adaptation, ranging from codes of conduct, best practices and even to regulations and modes of governance. They also believe that the process itself would produce the awareness that is currently lacking in the scientific community, as well as the self-education that has, in their opinion, thus far eluded life scientists working in the field. Furthermore, the Panel would produce a better consensus-building foundation, to move policy issues forward, namely towards building the networked web of protection that experts deem is necessary to combat the negative uses of biotechnology.

Conclusions

Most experts agree that biotechnology stands to be the leading technological field of the 21st century. They believe that advances in the biological sciences have the ability to solve many of the complex challenges confronting global health, food security, energy security and many other fields. At the same time, experts caution that biotechnology has an equally dangerous side, potentially leading to the development of new lethal weapons and other instruments that could undermine peace and individual freedom. To address these problems, experts believe that the balance between the positive and negative aspects of biotechnology should be governed by a protective web in the form of a network bringing together members of the scientific and industrial communities, state policymakers and relevant international organisations.

Outlining their views on the form and nature of the proposed protection web, experts reviewed many key themes to be addressed in future. The first concerns the perceived gap in awareness amongst life science practitioners of the dual-use nature of biotechnology, and the need to build a sense of responsibility from within the scientific community with regard to the potential negative consequences of proposed research projects. It is important to maintain a balanced approach to both the

positive and negative aspects of biotechnology; focus primarily on the negative aspects has led to a heavy-handed tone in discussions between industrialised and developing countries on biotechnology programmes. Also, it is considered that biodevelopment must be emphasised as logically anterior to any biosecurity measures. Experts believe that an acknowledgement of this grouping order diffuses tensions and creates a more favourable atmosphere for enhanced global cooperation. Finally, it was proposed that an international governance structure be established, and was noted with satisfaction that the Office of the UN Secretary-General is proceeding towards the launch of such a global initiative in the near future.

The UN Secretary-General's initiative on biosecurity was initially undertaken in an effort to combat terrorism. Under Secretary-General Ban Ki-moon and in the context of global challenges, it has evolved to include priorities on food security, energy security and global health, demonstrating that the language of the public good has begun to shape the approach to biotechnology. Possible models deemed appropriate for the initiative include those currently in operation under the auspices of Secretary-General Ban to combat malaria and to meet global health challenges, inasmuch as they bring together a multi-stakeholder coalition from the fields of business, government, science and civil society. The initiative against malaria appears to have been particularly successful o in rallying together many different actors from business, government and civil society to work with the existing UN global health architecture.

To think of biotechnology in terms of the public good has given rise to strategies on how best to promote the equitable distribution of the benefits of biotechnology, in a safe and secure fashion. This emphasis on the framing mechanism is important, to prevent recurrence of the negative experiences in dialogue witnessed in the past. Clearly, addressing the benefits to be generated for humanity is a far more galvanising and productive method of advancement on this issue.

The initiative launched in September 2009 was low-key, convening a small group of some 30 experts from the scientific and business communities. The purpose of the meeting was to hear experts from the heart of the biotechnology industry identify the focal issues on which the UN should concentrate for the future, and those areas in which the Secretary-General's involvement would most successfully galvanise opinion and provide added value. The meeting sought to arrive at a set of principles that would be acceptable across the biotechnology field on how best to foster international development while addressing safety and security concerns, and also to begin identification of prospective global champions across sectors, with a view to subsequently holding similar types of regional meetings for the same purpose. Also reviewed were the role these champions could play and their potential contribution in terms of advocacy, education and the ability to act as sounding boards for policy development. Finally, the gathering strove to document the lessons learnt on these issues within the UN system and to link it to the various existing initiatives.

BTWC 2008 Common Understandings

COMPONENTS	TOOLS	CHARACTERISTICS	ASSISTANCE NEEDED
Developing national biosafety and biosecurity frameworks	Accreditation	Measures should:	To enact and improve relevant legislation
Defining the role of different national agencies and bodies	Certification	Be practical	To strengthen laboratory infrastructure, technology, security and management
Building national, regional and international networks of relevant stakeholders	Audit or licensing for facilities, organisations or individuals	Be sustainable	To conduct courses and provide training
Taking better advantage of assistance already available	Training requirements for staff members	Be enforceable	To help incorporate biosafety and biosecurity into existing efforts to address disease
Improving bilateral, regional and international cooperation to build relevant capacity	Mechanisms to check qualifications, expertise and training	Be readily understood	
Enhancing the role played by the ISU	National criteria for relevant activities	Be developed with stakeholders	
	National lists of relevant agents, equipment and other resources	Avoid unduly restricting peaceful use	
		Be adapted for local needs	
		Be appropriate for agents being handled	
		Be suitable for work being undertaken	
		Make use of risk assessment, management and communication approaches	

OVERSIGHT CHARACTERISTICS

Develop national oversight frameworks:
To prevent agents and toxins from being used as weapons

1. To oversee relevant handlers, materials, knowledge and information
2. To oversee the entire scientific life cycle
3. To cover private & public sectors
4. That are proportional to risk
5. That avoid unnecessary burdens
6. That are practical and usable
7. That do not unduly restrict permitted activities
8. With the involvement of stakeholders in all stages of design and implementation
9. That can be harmonised regionally and internationally

EDUCATION & AWARENESS RAISING COMPONENTS

Formal requirements for seminars, modules or courses in relevant scientific education and training programmes that:

1. Explain the risks associated with the accidental or intentional harmful use of biology
2. Cover moral & ethical obligations
3. Provide guidance on the types of activities which could be prohibited
4. Are supported by accessible teaching materials, seminars, workshops, publications and audio-visual materials
5. Address leading scientists, managers and future generations of scientists
6. Can be integrated into existing national, regional and international efforts

NEXT STEPS FOR CODES OF CONDUCT

1. Complement national legislative, regulatory and oversight frameworks
2. Help guide science so it is not used for prohibited purposes
3. Further develop strategies to encourage voluntary adoption of codes

The 5P-Governance Matrix

Potential Biosecurity Measures	Principal Investigator	Project	Premise	Provider	Purchaser
Awareness Raising					
Education / Training					
Guidelines					
Codes of Conduct					
Regulation					
National Laws					
International Treaties					

Programme

Thursday, 25 June 2009

0900 – 0930	**Introduction** Ambassador Dr Fred TANNER, Director, GCSP Dr Stephen J. STEDMAN, MGI Project Co-Director
09h30 -10h30	**Panel: The Biological Century: New Advances, Opportunities, and Risks** Chair: Dr Stephen J. STEDMAN, MGI Project Co-Director Professor Malcolm DANDO, Professor of International Security, Department of Peace Studies, University of Bradford Mr Richard LENNANE, Head, Biological Weapons Convention Implementation Support Unit (ISU)
1030 – 1045	**Coffee Break**
1045 – 1200	**Discussion**
1200 – 1330	**Lunch at L'Attique Restaurant**

1330 – 1430	**Regulation: Self? National? Global?** Chair: Mr Marc FINAUD, Director of Short Courses, GCSP Dr Alexander KELLE, Lecturer in Politics and International Relations, University of Bath Dr Jean Pascal ZANDERS, Research Fellow, European Union Institute for Security Studies (EUI
1430 – 1500	**Discussion**
1515 – 1615	**Consensus Building: DNA for Peace and Establishing an IPCC-like Body** Chair: Ambassador Dr Fred TANNER, Director, GCSP Dr Abdallah DAAR, Senior Scientist and Director, Program on Ethics and Commercialization, McLaughlin-Rotman Centre for Global Health, University of Toronto Dr Stephen J. STEDMAN, MGI Project Co-Director
1615 – 1700	**Discussion**
1700 – 1730	**Conclusions: Dr Stephen J. Stedman, MGI Project Co-Director**
1730 – 1830	**Reception in the Salon Panoramique at L'Attique**

List of Participants

HE Ambassador Nobuyasu Abe, GCSP Foundation Council Member, Geneva, former UN Under-Secretary-General for Disarmament Affairs

Mr John Borrie, Senior Researcher and Project Manager, UNIDIR, Geneva

Dr Eva Busza, Principal Officer, Executive Office of the Secretary-General - Strategic Planning Unit (SPU/EOSG), United Nations, New York

Dr Silvia Cattaneo, Coordinator, Geneva Forum, Geneva

HE Ambassador Tim Caughley, Former Deputy Secretary-General of the Conference for Disarmament, Geneva

Dr Robin Coupland, Head of the Arms Unit Legal Division, International Committee of the Red Cross (ICRC), Geneva

Mr Sunjay Chandiramani, Intern, GCSP and Master's Student, Graduate Institute for International and Development Studies, Geneva

Dr Abdallah Daar, Senior Scientist and Director of the Program on Ethics and Commercialization, Professor of Public Health Sciences and of Surgery, McLaughlin-Rotman Centre for Global Health, University of Toronto

Professor Malcolm Dando, Professor of International Security, Department of Peace Studies, University of Bradford

Dr Stephen J. Del Rosso, Director, International Peace and Security, Carnegie Corporation of New York

HE Ambassador Barry Desker, Permanent Representative, Permanent Mission of Singapore, GCSP Foundation Council Member, Geneva

Dr Vojin Dimitrijevic, Director, Belgrade Centre for Human Rights, GCSP Foundation Council Member, Geneva

Mr Marc Finaud, Director of Short Courses, GCSP, Geneva

HE Ambassador Marius Grinius, Permanent Representative, Permanent Mission of Canada, Geneva

Dr Iris Hunger, Head, Research Group for Biological Arms Control, C. F. v. Weizsäcker Centre for Science and Peace Research, University of Hamburg

Ms Catherine Jefferson, Science and Policy Research Department, University of Sussex

Dr Alexander Kelle, Lecturer in Politics and International Relations, University of Bath

Mr Mohammed Koba, First Secretary, Permanent Mission of Indonesia, Geneva

Mr Richard Lennane, Head, Biological Weapons Convention Implementation Support Unit (ISU), Geneva

Ms Jenifer Mackby, Fellow, International Security Program, Center for Strategic & International Studies (CSIS), Washington DC

Professor Christine Mironesco, Department of Political Science, University of Geneva

Mr Gennady Neshin, Third Secretary, Permanent Mission of the Russian Federation, Geneva

Mr Leonid Ryabikhin, Executive Secretary, Committee of Scientists for Global Security and Arms Control, Moscow

Mr Abdulaziz Sager, Chairman, Gulf Research Center, Dubai, and Member, GCSP Foundation Council, Geneva

Ms Malike _elcuk Sancar, Counsellor on Disarmament, Permanent Mission of Turkey, Geneva

Mr David Spence, Political Counsellor, Delegation of the European Commission to the United Nations in Geneva

Dr Steve Stedman, Senior Fellow, Director, Ford Dorsey Program in International Policy Studies MGI Project and Co-Director, Center for International Security and Cooperation (CISAC), Stanford University

Ms Kathryn Stokes, Programme Manager, Secretary-General's Biotechnology Initiative, Executive Office of the UN Secretary-General, New York

HE Ambassador Tan York Chor, Permanent Representative, Permanent Mission of Singapore, Geneva

Ambassador Dr Fred Tanner, Director, GCSP, Geneva

HE Ambassador Silvano Tomasi, Apostolic Nuncio, Permanent Mission of the Holy See, Geneva

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Dr Ralf Trapp, International Disarmament Consultant on CBW arms control and disarmament, Geneva

Mr Helmut Walerius, Directorate-General 'Health', Consumers Health Threats Unit, European Commission, Brussels

Mr Reto Wollenmann, Policy Advisor on Arms Control and Disarmament, Directorate for Security Policy, Federal Department of Defence, Civil Protection and Sports, Bern

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