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Biosecurity

Task Forces on Strengthening Multilateral Security Capacity

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Foreword

We live in difficult times. Rapid socioeconomic changes, demographic bulges, and intertwined security crises are affecting us all, and most especially the poor. Criminal and violent organizations are gaining control over territory, markets, and populations around the world, complicating peacemaking and generating insecurity. States with ineffective and corrupt institutions prove too weak to deal with interlinked threats ranging from transnational organized crime to infectious disease. Meanwhile, the number of actual and aspirant nuclear-armed countries is growing, as is the likelihood that nonstate actors will acquire weapons of mass destruction through illicit global trade.

Global warming and environmental degradation particularly distress already impoverished regions. Fluctuating food and energy prices put people and governments to the test, while the demand for resources—notably water and energy—increases due to unprecedented development and population growth.

To this already gloomy picture, the year 2008 added tectonic shifts in the economic landscape. A devastating financial crisis is producing dramatic consequences with likely long-term impacts on economic development, aid, and emerging markets alike.

Yet, at a time when common efforts are needed more than ever, division and discord can be spotted in many multilateral institutions, from the United Nations to NATO and the European Union. Peace operations are under serious stress, while political disunity undermines the authority and effectiveness of the Security Council. The optimistic embrace of a "flat" world of responsible sovereign states is challenged by those who push for a return to exclusive state sovereignty and jealously guarded territorial integrity.

However, crises provide unparalleled opportunities for change. These moments are transitory, but they need to be seized upon to

put ideas into action, to strengthen the capacity to meet the challenges we face, which in today's globalizing world means more responsive, effective, and efficient multilateral mechanisms and policies.

In response to these challenges, IPI launched the **Task Forces on Strengthening Multilateral Security Capacity** in 2008. The purpose of these Task Forces was to suggest ideas for action to strengthen the capacity of the United Nations (UN) and its partners to deal effectively with emerging, multifaceted, and global challenges to peace and security. The Task Forces addressed not only the policy steps that are needed, but also the political and institutional strategies required to implement them. This strategic perspective has too often been the missing link in efforts to strengthen the UN system.

Given the links among security, development, and environmental challenges, the initiative opened with a symposium on Development, Resources, and Environment. The symposium provided a larger context for the work of the subsequent Task Forces, which focused on two core dimensions of the security concerns facing the UN and its partners: (1) Transnational Security Challenges and (2) Inter- and Intra-state Armed Conflict (see Annex 3 for details of the process).

The **IPI Blue Papers** are the product of this intense process of consultation, which engaged more than sixty UN member states, half of them at ambassadorial level, and seventy experts in a variety of thematic areas. It included the preparation of more than twenty-five background papers and fourteen multiday meetings. Each Blue Paper includes a section on why action to strengthen capacity in a particular area is needed and a section with ideas for action. The content is based on the Task Force discussions, but does not necessarily represent all the views articulated during the entire process. Although the institutional focus of the Task Forces was primarily the UN, this report aims to assist key stakeholders to prioritize and leverage the comparative advantages of the UN

and other multilateral institutions, including their ability to forge productive and sustainable partnerships with other groups and organizations.

While policy discussions on related topics are taking place in other fora, IPI brings to this initiative nearly forty years of constructive collaboration with the United Nations and its membership, as well as a more long-term strategic perspective than in-house and intergovernmental processes can offer. With these Blue Papers, IPI hopes to continue a process that will produce concrete steps toward stronger multilateral capacity in peace and security.

Despite the difficulties ahead, we believe that tomorrow's world needs more multilateral capacity, not less. It needs a stronger UN, capable of adapting and strengthening its capacity to address the realities of the twenty-first century. It needs a UN able to work with its partners and in particular with member states, which remain the first line of response to many of the threats discussed here.

This is the purpose of the IPI Blue Papers, and I am very pleased to introduce them to you.

Finally, I would like to thank most warmly the co-chairs of the Task Forces, the member-state participants, the experts, and IPI staff, without whose hard work and intellectual contributions the IPI Blue Papers would not have seen the light of day.

Terje Rød-Larsen
President, *International Peace Institute*
January 2009

Acronyms

BTWC	Biological and Toxin Weapons Convention (full title: Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological [Biological] and Toxin Weapons and on Their Destruction)
BW	biological weapons
CBMs	confidence-building measures
CWC	Chemical Weapons Convention (full title: Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction)
FAO	Food and Agriculture Organization of the United Nations
IAEA	International Atomic Energy Agency
ICRC	International Committee of the Red Cross
IHR	international health regulations
ISU	Implementation Support Unit
NPT	Nuclear Non-Proliferation Treaty (full title: Treaty on the Non-Proliferation of Nuclear Weapons)
OIE	World Organisation for Animal Health *(Organisation Mondiale de la Santé Animale)*
OCHA	United Nations Office for the Coordination of Humanitarian Affairs
OPCW	Organization for the Prohibition of Chemical Weapons
SARS	severe acute respiratory syndrome
UN	United Nations

UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNODA	United Nations Office for Disarmament Affairs
UNODC	United Nations Office on Drugs and Crime
UNSC	United Nations Security Council
WHO	World Health Organization
WCO	World Customs Organization

Executive Summary

Unprecedented progress in biotechnology holds the prospect of historic improvements in the welfare of humankind. Used responsibly, biotechnology can help address food insecurity, improve human health, provide solutions for environmental degradation, and help countries leapfrog in technological development. Used carelessly, or misused deliberately, biotechnology could inflict considerable human suffering—from the disastrous effects of bioweapons, to the accidental and deliberate spread of disease by state and nonstate actors.

States, international organizations, industry, and the scientific community have so far failed to address effectively the challenges emerging from rapid biotechnological development. At the international level, there is no robust regulatory framework to prevent or mitigate the inherent risks, while expanding the benefits, of the biotechnological revolution.

The multilateral system faces multiple challenges: (1) to ensure adequate implementation of existing norms, especially as reflected in the *Biological and Toxin Weapons Convention* (BTWC); (2) to develop new norms that are effective in the face of rapid technological change; (3) to ensure that the benefits of the biotechnological revolution are equitably shared; and (4) to ensure effective and coordinated prevention measures and crisis response.

IDEAS FOR ACTION

I. **Foster a paradigm shift:** States need to move beyond existing notions of biosecurity as a purely intergovernmental affair, toward an understanding of it as a transnational challenge with strong security and developmental impacts involving multiple stakeholders and requiring coordinated and integrated responses. Biosecurity should be understood as a product of responsible behavior by a wide range of state

and nonstate stakeholders through interlocking systems of regulation.

II. **Create a global forum:** Revitalize efforts to create a global forum at the United Nations, bringing together key state and nonstate stakeholders for a focused and ongoing global discussion of how to equitably share and expand the benefits of biotechnology, while managing the risks of accidental or deliberate misuse.

III. **Reframe the concept of verification:** Encourage verification measures in the use of biotechnologies by reframing the concept as one in need of transparency, and as a means by which value can be created for the private sector through the public trust in products and services generated by accreditation mechanisms and certification services.

IV. **Institutionalize incentives for transparency:** Explore the establishment of a permanent home for verification and promotion of the BTWC. Such a mechanism could commission an independent assessment of the impacts of biotechnical developments, help ensure transparency in biological-transfer systems, and investigate potential breaches of treaty norms. It might also serve as a tool for improved monitoring, and for the coordination, of crisis-response mechanisms and capacity-building assistance.

V. **Improve multilateral coordination:** Improve multilateral coordination and information sharing between and among institutions and stakeholders. For example, by the creation of a UN Executive Committee on Biosecurity and Public Health, or by ad hoc interorganizational information-exchange mechanisms, such as briefings by the Director of the World Health Organization (WHO) of the Security Council.

VI. **Equip the UN to understand biological risk:** Empower the UN to host a meaningful debate on biosecurity challenges by

ensuring that it has adequate scientific expertise on biological risks, and by providing independent scientific advice to the Secretary-General and the Secretariat on issues relating to the biotechnological revolution.

WHY ACTION IS NEEDED

The Challenge of Biosecurity

1. Recent years have seen exponential growth in applied scientific knowledge in the field of biotechnology. The emergence of a biotechnological revolution has been widely recognized by governments, industry, and the scientific community as generating prospects for rapid advances on a number of fronts, such as improving human health, addressing food insecurity, and alleviating environmental degradation.

2. Yet, the growth and evolution of biotechnology is also characterized by uncertainty. In a world of increased diffusion of technologies and expertise, increased mobility, and greater electronic interconnectedness, managing biological risk is an increasingly difficult task. Advancements in biotechnology hold numerous risks: for example, (i) the deliberate misuse by states and nonstate actors of biological agents and technologies; (ii) the accidental outbreak of disease; and (iii) potentially harmful impacts on human, animal, plant, or ecological health. It remains unclear how to ensure that the fruits of biotechnology advances are equitably shared, while safeguarding against misuse and unintended negative implications. And it remains unclear what role the multilateral system—especially the United Nations—can play in helping to achieve that outcome.

3. The term *biosecurity* has evolved simultaneously alongside the biotechnological revolution and taken on different meanings in different contexts. The most commonly referred to definition in the context of the *Biological and Toxin Weapons Convention* (BTWC) defines biosecurity as security-enhancing mechanisms to "establish and maintain the security and oversight of pathogenic microorganisms, toxins and relevant resources."[1] However, increased awareness of developmental impacts of biotechnology has expanded the term to consider public-health aspects of the biotechnological

revolution, as well as the question of equitable access to the benefits of biotechnology.[2]

4. A key challenge across all three areas of risk commonly associated with biotechnology—deliberate misuse, accidents, and systemic impacts—is to improve transparency in stakeholder access to and sharing of biotechnologies, biological agents, and biotechnological expertise. The interconnectedness of the challenges posed in these different areas requires a response that is multidimensional and comprehensive in its approach.

5. In the area of the misuse of biological agents, the multilateral system faces challenges in (i) ensuring adequate implementation of existing norms, especially as reflected in the BTWC; (ii) developing new norms that are legitimate and effective in the face of rapid technological change, especially given its intergovernmental focus and limited cooperation with nonstate actors, such as pharmaceutical and biotechnology companies, universities, hospitals, and research organizations; (iii) ensuring effective and coordinated capacity-building assistance; and (iv) ensuring effective and coordinated prevention and crisis response.

6. The norm against state military use of biological agents is strong, but the machinery in place to ensure its implementation is weak. The BTWC lacks the effective international machinery necessary to oversee its implementation and enforce its provisions. In its current state, the BTWC resembles a gentleman's agreement more than a rigorous control regime. The three-person Implementation Support Unit established by the BTWC Review Conference in 2006,[3] housed within the UN Office for Disarmament Affairs (UNODA) in Geneva, is not a robust substitute for a fully fledged verification organization, analogous to the IAEA or OPCW (with roughly 1,500 and 500 staff respectively). There is no home institution responsible for promoting the peaceful uses of biotechnology

and strategies for reducing biological risk, nor for developing mechanisms to ensure transparency and accountability by stakeholders.

7. Yet there are significant practical obstacles to the creation of a centralized verification or transparency mechanism. In particular, it is unclear how any such organization would "verify" compliance by states, given that biological agents can be quickly reproduced and used as weapons (unlike other weapons systems traditionally subject to verification regimes). Disarmament is made problematic by the need for states to maintain cultures of biological agents for detection, vaccination, and prophylactic purposes, and there has been significant historical opposition from key states to strong oversight arrangements at the international level. Still, there may be an opportunity for fresh thinking on the modalities of possible clarification mechanisms, given recent signs of support for broader disarmament initiatives, and calls from both states and private actors for a coordinated global framework.

8. The Security Council took steps to prevent nonstate misuse of biological agents through the establishment of the 1540 Committee in 2004.[4] But the 1540 Committee suffers from certain limitations. Its emphasis on nonproliferation is seen by some states as hard to reconcile with the promise in the BTWC of the promotion of scientific and technological exchange for peaceful purposes. And its reporting arrangements are seen as creating excessive burdens on states, yielding little tangible progress or assistance, and sometimes leading to politicized assessments of states' efforts.

9. Existing regimes also focus entirely on working with and through state actors, while private actors play an increasingly important role in creating, transferring, and mitigating biological risk. In 2006, then Secretary-General Kofi Annan proposed the creation of a "global forum"[5] to bring together

key actors to consider how to ensure that biotechnology serves the common good and to promote an equitable sharing of the fruits of biotechnology. Such a global forum could capitalize on the universality of the United Nations to generate new momentum on this issue. It could serve as a platform to survey key actors in the biotech industry and beyond on what the priorities of the international community should be moving forward. And it could provide a forum for devising strategies for expanding the capacities of developing countries and economies in transition to participate in the biotechnological revolution.

10. Still, many modalities and functions of such a forum remain to be clarified, particularly how nonstate actors would be selected for participation. In comparison to other disarmament fields, such as the nuclear and chemical disarmament, the number of actors with access to relevant resources is extremely large. It is estimated that roughly 1,500 state-owned and commercial culture enterprises worldwide maintain, exchange, and sell samples of microbes and toxins for scientific and biomedical research.[6] A global forum on biosecurity could provide a platform for interaction between such private and public actors on how to set global standards for equitable sharing of biotechnological goods, and on how to prevent and mitigate accidental or deliberate misuse of biological agents.

11. But effective management of biological risk would have to address not only deliberate misuse of pathogens, but also the spread of naturally occurring infectious disease and pandemics. Since the entry into force of the BTWC in 1975, fewer than 100 people have been killed by deliberate application of pathogens or toxins. Notably, some of the most potent agents, such as smallpox, ebola, and anthrax, are either difficult to obtain or difficult to cultivate for deliberate misuse.[7] In contrast, 25 percent of all deaths worldwide are

due to infectious disease, such as malaria, tuberculosis, and HIV/AIDS.[8]

12. In the area of accident and disease, the multilateral system faces challenges primarily in relation to coordination between a range of existing mechanisms for building public health, customs, and laboratory capacity and in responding to the outbreak of disease. Such mechanisms include the World Health Organization (WHO), the World Organisation for Animal Health (OIE), the Food and Agriculture Organization (FAO), United Nations Development Programme (UNDP), the World Customs Organization (WCO), and private actors such as philanthropic foundations.

13. WHO's revised international health regulations (IHRs)[9] are widely regarded as providing credible and effective arrangements for responding to public-health emergencies of international concern. At the same time, there are concerns that such regulation should not disadvantage states by requiring them to share information and samples that may be commercially exploited by other actors, or by unduly exposing them to economic or health burdens. The multilateral system will need to ensure an ongoing supply of effective capacity-building assistance in public-health systems to overcome such concerns. This poses significant coordination challenges, especially with the private sector. There is also a need for improved integration between surveillance of and responses to threats to human, animal, and plant health, and for capacity-building efforts across these sectors. Proposals such as the One Health Initiative may begin to address these needs.[10]

14. On a broader level, further thinking is needed to identify what role the multilateral system might play in ensuring that biotechnology does not have unintended lasting impacts on human society and the natural world. More thinking is also needed on how to make certain that technological change is

equitably managed and shared, providing broader access to the benefits of modern biotechnology.

15. This may require rethinking social approaches to biosecurity, for example, by beginning to frame it as a complex public-order issue rather than either a "security" or a "development" issue. Framing biosecurity as a public-order issue might facilitate: (i) building support for control measures, such as quarantine, that protect public order; (ii) taking steps to ensure accountability and a sense of responsibility by a wide range of stakeholders, for example, through portraying biosecurity as a matter of corporate social responsibility; and (iii) reframing global regulatory frameworks as collective risk-pooling and insurance strategies.

16. It may be useful to tackle each aspect of this multidimensional challenge separately. Yet there are also important cross-cutting considerations that should be kept in mind: to date, for example, the multilateral system has lacked the necessary scientific awareness to take a forward-looking approach to biosecurity issues generally, and to risk-mitigation strategies more specifically. Equipping the system with appropriate scientific expertise may be a simple first step toward a more comprehensive global response to the challenges and opportunities of the biotechnological revolution.

WHAT SHOULD BE DONE

Ideas for Action

I. FOSTER A PARADIGM SHIFT

17. **Utilize the UN's "bully pulpit":** The UN is well-placed to encourage a global debate on how to deal with tomorrow's biosecurity challenges. To start such a dialogue, the UN Secretary-General could give a major public address, outlining the enormous potential as well as the many risks associated with the biotechnological revolution, and provide a forward-looking view on how both opportunities and challenges could be addressed through a multiparty strategy involving private and public actors.

18. **Rethink the concept of biosecurity:** A paradigm shift requires moving beyond the existing notion of biosecurity as a purely intergovernmental affair, toward an understanding of it as a transnational challenge with strong developmental and security impacts. Meeting this challenge would require coordinated and integrated responses from both public and private institutions. Biosecurity should then be understood as a product of responsible behavior by a wide range of state and nonstate stakeholders through interlocking systems of regulation.

19. **Equip the multilateral system to understand biological risk:** Multilateral institutions cannot provide a 100-percent guarantee against biological risks, but they can provide frameworks for decentralized collective security. This requires, however, that they adequately understand the nature of the problem and take appropriate steps to ensure accountability by key stakeholders. Outside research organizations should be encouraged to convene informal meetings to explore how to equip the multilateral system with the necessary scientific awareness to understand both the perils and possibilities of biotechnology.

20. **Invest in political leadership:** There is a need for leadership at a global level to promote new thinking and turn it into action. At the UN, that leadership might come from the Secretary-General, individual or groups of states, and/or from the UN's High Representative on Disarmament. Leadership could also come from relevant expert bodies, such as the WHO, the FAO, and the OIE.

21. **Utilize the lead-up to the 2011 Review Conference to generate new thinking:** The 2011 Review Conference of the BTWC would be a good occasion for fostering such a paradigm shift. The period leading up to the review should be used to encourage scientific, political, and entrepreneurial initiatives aimed at equipping the BTWC adequately to meet the challenges of the twenty-first century.

II. CREATE A GLOBAL FORUM

22. **Encourage a focused international debate:** To date, there has been no global platform for a focused, ongoing international debate on how to prevent rapid biotechnological developments from outpacing regulatory responses. There is also no forum that brings together the various stakeholders—governments, industry, science, public health, and the general public—to consider how the fruits of biotechnology can be equitably shared, while reducing the risks of accidental or deliberate misuse.

23. **Reinvigorate and develop further the 2006 global forum initiative:** It is time to develop further the global forum initiative as presented in Saint Gallen, Switzerland, in November 2006.[11] Such a forum could help in building bottom-up strategies for realizing a paradigm shift that encourages transparency and a sense of responsibility by all stakeholders. It could also assist in setting the stage for future negotiations on a set of global biosecurity standards

that restrict access to dangerous pathogens and help share the benefits of the biotechnological revolution.

24. **Build on best practices:** The guiding principles for such a forum should not be developed in a vacuum, but should be built upon best practices developed by relevant expert bodies capable of formulating biosecurity guidelines, such as the WHO, the FAO, and the OIE.

25. **Work toward specific outputs:** The forum should work toward specific outputs, such as harmonized lab-safety standards; strengthened ethical norms in the biotech industry and beyond; equitable access to the knowledge and development of biotechnology; improved mechanisms for global disease surveillance and response; and best practices for the security and oversight of biological toxins and pathogens.

III. REFRAME THE CONCEPT OF VERIFICATION

26. **Reframe the term "verification":** There is a need to move beyond the taboo that has developed around the term "verification," by reframing it as a need for transparency and by creating mechanisms to produce incentives for transparency. For industry, this may mean linking transparency to market forces, for example, through developing accreditation mechanisms and certification services. For states, this may mean linking transparency to capacity building, possibly through connecting reporting obligations to technical assistance.

27. **Use carrots rather than sticks:** The best way to promote international compliance with biosecurity standards is not by punishment, but by providing incentives. Global standards should strive to strengthen the weakest links by providing sustained capacity building for those states with the least secure facilities and by setting realistic goals that do not discourage compliance.

28. Create incentives for private actors to work with states and vice versa. There is a need to revisit the role of private-sector actors in verifying access to biological agents, the use of biotechnology, and capacity building. Private actors should be encouraged to work together with states, and vice versa, to develop transparency-enhancing partnerships and to develop joint strategies for crisis management.

IV. INSTITUTIONALIZE INCENTIVES FOR TRANSPARENCY

29. There is a need to revisit how incentives for transparency, particularly relating to misuse of biological agents and biotechnologies, might be institutionalized.

30. **Consider a permanent home for the BTWC:** The international community should consider whether a permanent home for verification and promotion of the *Biological and Toxin Weapons Convention* is required; and what functions such an institutional arrangement would entail. At least three functional areas should be considered: (i) independent assessment of the impacts—positive and negative—of technological developments; (ii) ensuring transparency in stockpiles and transfer systems; and (iii) investigation of apparent breaches of treaty norms.

31. **Perform an inventory of existing mechanisms:** Similarly, there is a need to assess whether incentives for transparency in crisis-response mechanisms and capacity-building assistance are adequately coordinated. A good place to start might be to perform an inventory of existing international, regional, and private mechanisms involved in crisis response and capacity building. Such an inventory would be helpful for identifying overlapping efforts and possible synergies.

V. IMPROVE MULTILATERAL COORDINATION

32. **Promote coordination and information-sharing:** Coordination and information-exchange among the UN Secretariat, agencies, funds, and programs should be encouraged and facilitated. One precedent to learn from could be the One Health Initiative, which works to establish closer collaboration among medical, veterinary, and environmental stakeholders.

33. **Establish an executive committee on biosecurity:** Consideration should be given to establishing a UN Executive Committee on Biosecurity and Public Health (for example including FAO, OCHA, UNDP, UNICEF, the UN Office on Drugs and Crime [UNODC], and WHO) similar to the Executive Committees on Peace and Security and on Humanitarian Affairs. A broader mechanism for exchange of information with non-UN bodies (such as the OIE, WCO, or INTERPOL) should also be considered.

34. **Encourage more routine interaction among the diverse parts of the UN system:** Decision makers in New York, Geneva, and other parts of the UN system should be encouraged to engage in more routine interaction on these issues, for example, through briefings to the Security Council by the Director-General of the WHO.

VI. EQUIP THE UN TO UNDERSTAND BIOLOGICAL RISK

35. **Empower the UN through improved access to scientific expertise:** The United Nations is well placed to initiate, facilitate, and pursue a dialogue on biological risk management. It has the universal membership, the legitimacy, and the capacity for outreach that are needed. However, to fully equip the multilateral system, the world body, especially the UN Secretariat, should have access to adequate, independent

scientific expertise to understand biological risk in all its forms and complexity.

36. **Assist the Secretary-General in taking a forward-looking approach:** The Secretary-General should be encouraged to create an informal Scientific Advisory Council or to explore the appointment of a Scientific Adviser. This would permit UN leadership to take a broader and more forward-looking approach to the challenges of the biotechnological revolution, beyond the limited mandates of the existing UN bodies and the interests of individual member states.

Conclusion

37. The biotechnological revolution is here to stay. Utilized responsibly, it has the potential to bring unprecedented benefits to humanity and to build better lives for people around the world. But in the wrong hands, or by negligent or deliberate misuse, biotechnology poses a severe threat to international peace and security. States, industry, the scientific community, and international organizations should join in a common search for better ways to work together to support the benefits of biotechnology, while actively preventing and mitigating the risks.

38. The lack of international harmonization of biosafety standards has opened up worrisome security gaps that could be exploited by state and nonstate actors. Existing regulatory frameworks and verification measures are outdated, and are easily outpaced by rapid technological developments. A focused international debate should reassess the dual nature of biotechnology, while identifying measures to close existing regulatory loopholes before they are exploited for nonpeaceful purposes.

39. State-based legislation should be complemented by improved information-sharing; enhanced mechanisms for disease

surveillance and response; improved implementation of existing norms, such as the BTWC; the development of new, more efficient, norms; and more effective and coordinated capacity-building assistance at the international level. This agenda can be achieved only through a multiparty strategy, bringing together states, industry, international organizations, and the scientific community to jointly consider how to address the possibilities and the perils of the biotechnological revolution.

Endnotes

1. See the Implementation Support Unit (ISU) for the BTWC's background information note. BTWC, "National Measures and Views on Biosafety and Security," August 20, 2008, available at www.opbw.org/new_process/mx2008/BWC_2008_MX_Docs/BWC_MSP_2008_MX_WP.28_En.pdf .

2. WHO's "Laboratory Biosafety Manual," notes that, in public health settings, biosecurity entails the "protection of microbiological assets from the theft, loss or diversion, which could lead to the inappropriate use of these agents to cause public health harm." See WHO, "Laboratory Biosafety Manual, Third Edition," 2004, available at www.who.int./csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/ .

3. See the "Final Document of the Sixth Review Conference of the Biological Toxin Weapons Convention," 2006, available on the BTWC website at www.opbw.org/rev_cons/6rc/docs/6/BWC_CONF.VI_6_EN.pdf .

4. On April 28, 2004, Resolution 1540 was unanimously adopted by the UN Security Council, obliging states to refrain from supporting nonstate actors in "developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems." The 1540 Committee was established to oversee the implementation of the resolution. See UN Security Council Resolution 1540 (April 28, 2004), UN Doc. S/RES/1540.

5. See Kofi Annan, "St. Gallen Acceptance Speech," St. Gallen, Switzerland, November 18, 2006, available at www.stgallen-symposium.org/archive/kofi_annan.htm .

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8. Sarah B. Watstein and John Jovanovic, *Statistical Handbook on Infectious Diseases* (Westport, CT: Greenwood Press, 2003) p. 223.

9. World Health Organization, "International Health Regulations," 2005, available at www.who.int/csr/ihr/en/ .

10. The One Health Initiative by the American Veterinary Medical Association seeks to address contemporary health challenges created by the convergence of human, animal, and environmental domains. The initiative seeks to promote increased information exchange and enhanced collaboration between the veterinary and human medical professions. See American Veterinary Medical Association, "One Health: A New Professional Imperative," 2009, available at www.avma.org/onehealth/ .

11. Annan, "St. Gallen Acceptance Speech."

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Annex 1: Background Non-paper

APRIL 1, 2008

It is difficult to think of an area of major human activity that is not affected by developments in biology and biotechnology. These developments allow societies to leapfrog a number of the traditional stages in economic, scientific, and societal development to compete or find a significant niche in global markets and operate on the leading edge of science and technology. Indeed, over the past five to ten years, some developing countries have moved from being importers of biotechnology to being net exporters. Yet there are also risks associated with the development of biotechnology:

- increasing costs of medicine reinforcing socioeconomic inequality;
- social debates over the privacy of genetic data, which are likely to be exacerbated by institutions that provide for collective or individual safety nets redefining risk;
- impacts of genetic modification on local and regional ecosystems may make people dependent on a single supplier of genetically modified organisms;
- risks of military use and misuse.

It is also still far from clear how the newfound benefits of biology and biotechnology will be equitably distributed among and within newly developed societies, perhaps leading to new inequalities and sources of conflict. The rate of improvements and discoveries in biology and biotechnology is exponential and it is therefore hard to envisage what may be possible five, ten, or twenty years from now—let alone create global regulatory frameworks for mitigating these risks.

1. **What are the current policy and institutional shortcomings in multilateral security capacity for biosecurity?**
    - It is important to emphasize that while there are potentially severe risks associated with the proliferation of biotechnology,

the norm established against the proliferation and use of biological weapons is in fact very strong: no state publicly admits to a biological-weapons (BW) program or stockpiles.

- In fact, the perceived threat posed by biological warfare or other forms of deliberate dissemination of pathogens has, if anything, recently increased. Three major groups of factors contribute to this:
  - lack of transparency about past and present biological-weapon-related activities, causing concern about state activities;
  - scientific and technological innovations; and
  - the proliferation of biodata, materials, and expertise into the hands of nonstate actors, both licit (universities, research organizations, and commercial organizations) and illicit (including criminal and terrorist networks).
- The core international legal instruments governing the prohibition on BW use, acquisition, and possession (the 1925 Geneva Protocol banning the use of chemical and biological weapons and the 1972 *Biological and Toxin Weapons Convention* [BTWC]) are widely viewed as inadequate to address these concerns.
- The 1925 Geneva Protocol does not place any restrictions on the development, acquisition, or stockpiling of chemical or biological weapons, nor does it contain any provisions to oversee and enforce compliance or to investigate violations.
- The BTWC contains stronger provisions:
  - Article I of the BTWC specifies that state parties can never acquire or retain biological and toxin weapons under any circumstances, and is now formally interpreted also to prohibit BW use.
  - Article II requires states to destroy or divert all BW to peaceful uses.
  - Articles III contains nonproliferation provisions that apply to both state and nonstate actors in territory under the control of a state party.
  - Article IV obliges a state party to transpose Articles I-III

into domestic legislation in order to make them applicable to natural and legal persons on territory under its control.

- Article V provides for consultation and cooperation between parties.
- Article VI provides for reference of unresolved disputes to the UN Security Council for investigation—a mechanism that has not been used.

- BTWC Article X gives the parties the right to participate in the fullest possible exchange of equipment, materials, and scientific and technological information of relevance to the convention for peaceful purposes.
  - This has become contentious because in the view of some states it may contribute to a state acquiring an offensive biological-warfare capability (e.g., in terms of a surge production capability for BW) or developing novel types of agents.
  - The export controls imposed by a number of industrialized states to prevent BW proliferation are viewed by some developing countries as discriminatory and a violation of the obligation not to hamper their economic or technological development.
- Following the terrorist attacks of September 11, 2001, the UN Security Council adopted several resolutions on terrorism, including UN Security Council Resolution (UNSCR) 1540 on April 28, 2004.
  - This requires all UN members to refrain from assisting nonstate actors with the acquisition of biological, chemical, and nuclear weapons and their delivery means. To this end, all states must set up domestic controls to prevent such proliferation to terrorist entities, establish appropriate controls over related materials, and adopt relevant legislative measures.
  - With regard to BW, UNSCR 1540 in essence reiterates the provisions of Articles III and IV of the BTWC. It is, however, more detailed in outlining the types of measures that could be promulgated and implemented in order to meet the requirements. Most significantly, UNSCR 1540 extends the

obligations to all UN members and not just to those states party to the BTWC.

- Nonetheless, the machinery established to oversee implementation of UNSCR 1540 cannot overcome certain core shortcomings of the existing international regimes.
- The BTWC lacks an international, institutional setup to oversee its implementation and enforce its provisions.
  - The absence of an international organization comparable to the International Atomic Energy Agency (IAEA) or the Organization for the Prohibition of Chemical Weapons (OPCW) means that parties to the BTWC will always have doubts about the convention's efficacy.
  - In addition, there is no promotion of the convention, no coordinated effort to promote the peaceful uses of biology and biotechnology or to assist state parties with their implementation requirements, and no development of mechanisms to enhance transparency.
  - At the 6th Review Conference (2006) the state parties agreed to set up the Implementation Support Unit (ISU). The ISU, which consists of three people, is no functional substitute for a fully fledged international organization.
- The BTWC has no verification tools:
  - In the final stages of the negotiation of the BTWC in 1971, the USA and the USSR dropped the modest verification proposals that had been proposed. Ever since, verification has been a contentious issue.
  - At the 2nd and 3rd Review Conferences (in 1986 and 1991 respectively) a number of confidence-building measures (CBMs) were agreed, but these are not legally binding. As a consequence, the participation rate has been low and the quality of the submissions varies greatly from country to country. Furthermore, they can be submitted in any of the six UN languages, but are not translated. This means that countries lacking resources do not have the ability to assess the submissions, which reduces the relevancy of the CBMs even further.

- In 2001 the negotiation of a legally binding protocol to the BTWC, which would have included a number of transparency-enhancing measures, collapsed. As a consequence, the idea of verification has been off the table. The term "verification" has even acquired a taboo quality.

- It also arguable that the BW threat is being inflated, making it more difficult for international treaties and institutions to address the security concerns.
  - Since the entry into force of the BTWC in 1975 fewer than 100 people have been killed by means of the deliberate application of pathogens or toxins (and most cases concerned crimes of passion or revenge).
  - Inflation of the threat to nightmarish proportions creates a political incentive for states to bypass multilateral treaties and institutions and rely on unilateral solutions.
  - However, while the risk of BW use may be small, the cost of a solution once usage has occurred may be very significant, making prevention a more cost-effective and safer alternative.
- Existing global health and biosafety regimes provide a very limited framework for the sharing of sensitive biological and biotechnological data, samples, expertise, and knowledge necessary for collective public health control arrangements.
  - Over recent years, some states have voiced increasing concern about global epidemic and public health control regimes, on sovereignty grounds.
  - Arrangements for sharing information, data, and samples are particularly contentious in the area of pandemic response, with particular concerns relating to the use of shared samples for research and development processes.
- Existing regimes also focus on working with and through state actors, while private actors (including universities, private hospitals, pharmaceutical companies, and research organizations) play an increasingly important role as the sites of sensitive biodata, samples, expertise, and knowledge.

2. Why have previous attempts to address these shortcomings failed?

- For a variety of reasons the international community has proved reluctant to strengthen existing international arrangements.
- State parties investigated and negotiated options for a comprehensive compliance and verification regime, but these efforts failed in 2001.
- Ever since the negotiation of the BTWC, it has been claimed that the convention is unverifiable.
- While the vision often reflects an ideological bent against intrusive verification and inspection mechanisms, it is not entirely without merit if the concept of verification is considered in its traditional functions:
  - Observation of the presence or the absence of a particular object at a certain location at a given time and time series will reveal compliance or noncompliance with the disarmament treaty; or
  - the establishment of material balances of certain dual-use goods with the aim of detecting and deterring diversion of these goods for illicit purposes.
- With respect to biological agents, neither approach is practical: as self-replicating organisms they may be stored and manipulated in minute quantities (which could be argued to be consistent with the legitimate purposes listed in Article I of the BTWC) and large volume production may be undertaken at the time of perceived necessity. With today's production capabilities there is no longer any need to stockpile BW.
  - Final determination of the weapons' purpose may only be possible from the moment the agent is filled into the munition.
  - Furthermore, it is argued that a significant biological threat comes from nonstate actors, such as terrorists and criminals. No international verification regime can deal with that security threat, it is claimed.
- Distinctions between malign and benign uses are more blurred than in other disarmament and counterproliferation fields.

- From a disarmament perspective, biological weapons are unique in the sense that the active ingredient (i.e., the agent) is required both for the offense (weapon filling) and the defense (detection, vaccines, and prophylaxis), making determination of weapons programs in violation of international agreements and arrangements much more complicated than in the nuclear and chemical weapons fields

- Since the end of the Cold War there has been a major paradigm shift from disarmament to nonproliferation, creating hostility between developed and developing countries, as the latter group views these measures as a contrary to the promise in the BTWC (and other arms-control and disarmament treaties) to promote scientific and technological exchanges for peaceful purposes.
  - Many developing countries and commentators also suggest that treating issues of the dissemination of biotechnology expertise and knowledge as a question of security, rather than through the lens of public health and development, is unhelpful.
- In comparison to other disarmament fields (chemical, nuclear), the number of stakeholders with access to relevant resources in the biological and biotechnological fields is relatively large. As a result, both the development and the implementation of new norms and existing norms is comparatively more difficult, not least since many of the newest stakeholders in the biotechnological field (particularly private stakeholders such as universities, pharmaceutical, agricultural, and biotechnology companies) were not involved in the development of existing norms and do not necessarily see themselves as potential participants in the corresponding regime.
- Yet states are reluctant to give private actors a significant voice in developing and implementing global control norms and monitoring, implementation, and verification regimes
  - No government or international organization could hope to monitor the tens of thousands of small biotechnology facilities spreading and migrating around the world. The number of facilities and the capability of the technology are ever growing, while the cost and size of the equipment drops steadily.

- Any framework for mitigating the risks associated with biotechnology must give a role not only to the traditional security sector, but also to public health, agriculture, law enforcement, and education sectors, as well as the international scientific community and commercial industry.

3. What policies and institutional renovations, including legal frameworks and financial arrangements, are needed?

- There is a need for a conceptual shift. Biosecurity cannot simply be considered as "biosafety + locks on doors." It must be understood as a product of effective regulation at the global, regional, national, and local levels.
  - This will include training and licensing, information management, awareness-raising, codes of conduct, disease surveillance, protocols for cooperation, and information sharing between health and law-enforcement agencies, export controls, transport regulation, and emergency preparedness and response.
- Norm implementation and verification cannot be achieved by governments or international organizations acting alone.
- There is a need for a uniform global framework to mitigate the potential risks from the proliferation of biotechnology and expertise in the manipulation of biology.
  - At present, there exists no global forum that brings together all the various stakeholders, despite calls for such a forum by then Secretary-General Kofi Annan at St. Gallen in late 2006.
  - Efforts by international actors (such as the ICRC's awareness-raising activities, the promotion of a voluntary code of conduct by the International Centre for Genetic Engineering and Biotechnology, and guidance provided by the World Health Organization, and UNCTAD) remain fragmented.
  - A meeting was held in Abu Dhabi in November 2007 to begin to build a global network between governments, international organizations, academic and research institutions, and the private sector to deal with the developments in the field of life sciences.
  - But these efforts to build a network are in their early

stages, and cannot provide a substitute for a permanent, formal framework providing a forum for discussion and an institutional home for awareness-raising, capacity-building and norm-implementing activities.

- In the industrialized world, the development of biotechnology is driven by market forces. This leaves important areas untouched because of the lack of immediate commercial interest. These biotechnology niche areas are being taken up by a number of developing countries, giving them the ability to deploy leading-edge activities in the life sciences and their commercial application. They lead to other international networks of technology exchanges, which the supply-side nonproliferation policies favored by industrialized nations do not capture. In order to prevent possible malicious application of these technologies, a global, multilateral regime that enhances transparency about activities in all states is in the interest of all states.
- There is a clear need for a meaningful institutional setup to support the norm against biological weapons.
  - The absence of an international organization in support of the BTWC has a major impact on the ability to strengthen the norm against BW. There is a lack of coordinated and sustained promotion of the convention, which has resulted in fewer state parties than the *Treaty on the Non-Proliferation of Nuclear Weapons* (NPT) or the CWC despite the fact that it has existed for over thirty years.
  - There is limited normative development and an absence of mechanisms to organize international cooperation for peaceful purposes among state parties. Furthermore, there is no partner to engage the scientific and industrial communities in norm- and regime-building.
  - One of the primary reasons to have a permanent institutional setup is to organize transparency with regard to relevant activities in order to reduce suspicions. In addition, any compliance concerns can be dealt with immediately within the appropriate organs of the international organization and avoids to the widest possible extent the involvement of the UN Security Council.

4. **What strategy is needed to achieve these renovations?**

- The area of biosecurity may provide an important opportunity for the UN to demonstrate its potential to add value in responding to transnational security challenges, because of a growing recognition of the need for a paradigm shift.
  - States and private actors are increasingly calling for a coordinated global approach that highlights the synergies between biosecurity and development.
  - States also increasingly recognize the need for arrangements that draw in nonstate actors in both norm development and implementation.
- There is a need for the same kind of innovative thinking that was applied to international regulation of the nuclear industry sixty years ago.
  - As in that era, the promise of level playing-fields and of technical capacity building may be the carrots that can help bring the widest possible number of actors into the regime.
  - But this will depend on the establishment of reliable international partners (as the IAEA has been in the nuclear field and the OPCW in the chemical field) to undertake diverse monitoring, technology transfer, and capacity-building roles.
- Also, there is no need to start from scratch: the BTWC regime already provides a strong normative basis for further regulatory efforts.
  - The 2006 BTWC review conference made some progress in generating a process that might provide the basis for renovation of the existing architecture.
  - In particular, state parties agreed a detailed new intersessional work program to help ensure effective implementation of the Convention until the Seventh Review Conference in 2011, addressing themes including national implementation; regional and subregional cooperation; biosecurity and biosafety; oversight, education, awareness raising, and codes of conduct; assistance and capacity enhancement; and assistance and coordination in cases of alleged use of

biological weapons.

- The real test of this approach will be whether these meetings produce meaningful forward progress and substantive impact on the regime development process, and do not simply amount to inconsequential information exchange.

- Although the Geneva Protocol and the BTWC are not UN treaties, there is a clear role for the UN to play in providing a forum to bring together all the relevant state and nonstate stakeholders to develop a common framework to mitigate biosecurity risks.
  - The scientific and professional communities, as well as the industry, were actively involved in the negotiation of the *Chemical Weapons Convention* because the verification regime was discussed in parallel with the ban on chemical weapons.
  - In order to achieve a similar outcome with regard to BW, there will be a need to (1) clarify that it is in the interests of the scientific and professional communities as well as the biotechnology and pharmaceutical industries to explicitly endorse such a ban and support transparency-enhancing measures, (2) devise a transparency-enhancing regime that offers incentives to those communities for participation in it, and (3) get them actively engaged in the design of such a transparency-enhancing regime.
- Currently the UN Office for Disarmament Affairs (through the BTWC Implementation Support Unit) takes responsibility for hosting the meetings of state parties to the BTWC. The main focus of these activities is on the development of the BTWC treaty regime (expert meetings, meetings of state parties, review conferences, etc.). Meanwhile a number of more recent developments relating to BW are undertaken by the New York branch of UNODA, including matters relating to terrorism, the implementation of UNSC Resolution 1540, etc. Care should be taken that both groups of activities do not become competing projects, preventing the future integration of UN action in the field of BW prevention and progress in the development of the BTWC.
- Independent thinking on ways of verifying the BTWC should be

stimulated.

- The absence of any meaningful tools for state parties to ascertain that other state parties are compliant is one of the BTWC's greatest weaknesses.
- Verification concepts are still very much rooted in Cold War thinking. Initiatives should be undertaken to stimulate independent and out-of-the-box thinking about the future meaning of verification. These insights should then be applied to the concrete case of biology and biotechnology, taking into consideration its unique characteristics (multiple stakeholdership, intangible technologies, rapid development) in order to maximize transparency about intent and balance scientific and commercial interests with necessary and realistic security requirements.

- Developing countries should be encouraged to elaborate their concrete expectations under Article X of the BTWC.
  - The debate on technology transfers in support of international cooperation and development under the BTWC has become an ideological encumbrance, which currently hampers any meaningful progress on the issue (and contributes to the diminished relevancy of the convention).
  - Relevant technology transfers already take place in the commercial sphere and under several international arrangements (including the World Health Organization, the Food and Agriculture Organization, the World Organisation for Animal Health, the Rio Convention, etc.). It is therefore necessary to determine which technology transfers are relevant to the BTWC in particular and then to organize those activities in such a way as to ensure full compliance with Article III (the nonproliferation obligation).
  - The creation of an international organization in support of the BTWC would offer the best guarantee of a meaningful implementation of Article X.
- Emerging and reemerging diseases pose a global challenge. In terms of their impact on societies, the consequences are similar to those that may result from an attack with biological weapons. The development of national health infrastructure and the promotion of regional and subregional cooperation in areas of

disease surveillance and detection as well as mutual assistance would be beneficial to all societies. On the global level, the capabilities and coordinating work undertaken by the World Health Organization, the Food and Agriculture Organization, and the World Organisation for Animal Health should be advanced even further. The opportunities offered by these organizations to assist with the rapid detection of deliberate outbreaks of disease should be further explored while respecting the specific missions of each of these organizations.

Jean Pascal Zanders with IPI

Annex 2: Reflections from the Opening Plenary Meeting

APRIL 7, 2008

1. **What are the current policy and institutional shortcomings in multilateral security capacity for biosecurity?**

- The concept of biosecurity is multidimensional—touching on wide-ranging issues of security, disarmament, risk prevention, public health, economic development, and research and private property rights.
  - The challenges posed by biosecurity can also be understood as encompassing both intentional and unintentional misuse of biological materials and technologies.
  - Ultimately, the way we frame the issue of biosecurity determines modes of response, strategies for implementation, and methods of verification and compliance.
  - The UN's "value added," "comparative advantage," and appropriate role will vary depending on how the issue is framed.
- Developments in biology and biotechnology have grown exponentially, potentially allowing societies to leapfrog stages in development. However, there are also a number of risks associated with the speed of innovation that have to be taken into consideration:
  - It is far from clear how the benefits from biology and biotechnology will be distributed among and within societies, potentially causing social tension and new conflict linkages.
  - The cost and complexity of research have increased substantially, contributing to rising global medicine prices, with a concomitant risk of exacerbating global socioeconomic inequalities.
  - With scientific and technological innovation follows the natural diffusion of technology, which carries the risk of proliferation of biotechnology for military use and misuse by state and nonstate actors.

- It is arguable that the perceived threat posed by biological warfare—and even bioterrorism—is inflated, making it more difficult for international institutions to address other biosecurity concerns, such as those associated with emerging and reemerging disease.
  - Since the entry into force of the *Biological and Toxin Weapons Convention* (BTWC) in 1975, fewer than 100 people have been killed by the deliberate application of pathogens or toxins.
  - In contrast, the spread of infectious disease still constitutes the greatest pressure on human evolution. Annually, 25 percent of fatalities worldwide are due to infectious disease, killing approximately 3,000 people every two hours on average.
  - Clearly, balancing our understanding of the three different types of threat relevant to biosecurity, including disease, state-originated attack, and nonstate terrorism will be very important in developing appropriate responses.
- While the normative framework against the proliferation and use of biological weapons is strong, the treaties and international agreements remain weak:
  - The core legal instruments governing the prohibition on BW use (the 1925 Geneva Protocol and the 1975 BTWC) are widely viewed as inadequate in operationalizing the norm against proliferation and use of BW.
  - The BTWC currently lacks adequate human resources and effective international, institutional arrangements to oversee its implementation. The present BTWC Implementation Support Unit (ISU) established in 2006 consists of three persons. This is to be compared with the International Atomic Energy Agency (IAEA) with approximately 1,500 staff, and the *Chemical Weapons Convention* (CWC) with 500 staff.
  - The BTWC has no verification tool. It more closely resembles a gentleman's agreement than a deep-control regime. The issue of verification remains contentious and a source of strife among state parties.
  - UNSC Resolution 1540 adopted in 2004 has extended a number of key BTWC obligations to UN member states.

Nonetheless, the 1540 Committee to which UN members must report the status of their legislation has no tools of verification and cannot overcome certain core shortcomings of the existing international regimes.

- Current mechanisms and tools of verification stem from the Cold War era and are largely outdated and ineffective with regard to the challenges posed by biology and biotechnology. They are difficult to adapt to situations characterized by multiple stakeholdership, intangible technologies, and rapid development.

- In addition, no effective system and mechanism for sharing of information and data relating to biological materials and technologies exists today:
  - Existing international regimes provide a very limited framework for the sharing of necessary biological and biotechnological data, samples, expertise, and knowledge for collective security and public health arrangements.
  - Existing regimes may in fact discourage the sharing of such information lest it lose its value as private property.
  - Existing regimes also focus on principally working with and through state actors. This is despite the fact that private actors (including universities, private hospitals, pharmaceutical companies, and research organizations) play an increasingly important role as the sites of sensitive biodata, samples, expertise, and know-how. Private actors do not necessarily feel a sense of buy-in to the international control regimes that they had no direct part in developing.
- At the same time, multilateral mechanisms to prevent and respond to global health threats such as influenza pandemic outbreaks and the spread of infectious and multiresistant disease, have proved effective in a number of areas:
  - The UN specialized agencies responsible for animal and human health (the Food and Agriculture Organization and the World Health Organization) are today well positioned to coordinate a global response to emerging diseases. In the case of WHO, this was illustrated during the SARS crisis, and the FAO conversely in reducing the threat of H5N1 virus (avian flu) and other diseases such as BSE (mad cow disease).

- Other mechanisms include the OIE (World Organisation for Animal Health – formerly *Organisation Mondiale de la Santé Animale*) which is a strong advocate of the BTWC and works closely with the FAO and WHO on preventive measures.
- The WHO pandemic prevention and response regime has had an important role in strengthening coordination and rapid response mechanisms at global, regional, and national levels, though it has not been entirely immune to controversy, especially over the intellectual property implications of information sharing.

- These measures need to be complemented by:
  - Reinforcing transparency-enhancing mechanisms between countries and institutions involved in responding to the risk of pandemic influenza, and supporting the role of multilateral institutions, such as WHO, FAO, and OIE, in leading this effort.
  - Strengthening multilateral capacities and coordination mechanisms for early detection of and rapid response to global health threats.
  - Increasing the collaboration between countries in developing national and regional plans for avian influenza control and pandemic influenza preparedness within the framework of a coherent international risk-management system.
  - Better coordination of risk communication and harmonizing routine surveillance systems worldwide.

2. Why have previous attempts to address these shortcomings failed?

- For a variety of reasons the international community has proved reluctant to strengthen existing institutional arrangements.
- There is a lack of trust amongst state parties in the arena of BW control and the transfer of biological and biotechnological information. This trust might be built and strengthened through effective verification, compliance, and monitoring mechanisms, but states have perceived little incentive to take such measures.
- While information technology advances have improved the breadth, availability, and quality of open-source information,

the arrangements for sharing of information, data, and samples between key biosecurity stakeholders, particularly in the area of pandemic response, remain contentious and a source of reluctance.

- In addition, the latest attempts in 2001 to strengthen a number of transparency-enhancing BTWC measures failed. As a consequence the idea of verification has been taken off the table. The term "verification" has acquired a taboo quality.
- The current international treaties including the BTWC have not been successful in engaging nonstate actors and the pharmaceutical industry. Biosecurity is still largely state-centric and treated as an intergovernmental affair, contributing to a widening of the gap between the state parties of the BTWC and the scientific community.
- This state-centered approach has also failed to take advantage of the possibilities offered by market forces, as for standard-setting and implementation.
- However, there are signs that states and private actors are increasingly calling for a coordinated global approach to biosecurity. Yet, reluctance still prevails in giving private and nonstate actors a significant voice in developing and implementing global control norms and monitoring, implementation, and verification regimes.

3. What policies and institutional renovations, including legal frameworks and financial arrangements, are needed?

- There is a need for a conceptual shift.
  - Biosecurity cannot simply be considered as a purely intergovernmental affair, excluding key private and nonstate stakeholders.
  - Norm implementation and verification cannot be achieved by states or international organizations alone.
  - Biosecurity should be understood as a transnational challenge, requiring coordinated and integrated responses from both public and private institutions.
- The fast-moving nature and developments in biology and biotechnology imply that international norm setting and

regulation must also become more dynamic:

- The impact of biological and biotechnological innovation on a wide range of social structures, including ethical standards, environmental systems, the global market of commodities and food, remains vastly understudied.

- There is a need for a uniform global framework to mitigate the potential risks from the proliferation of biotechnology and expertise in the manipulation of biology:
  - At present, there exists no global forum that brings together all the various stakeholders, despite calls for such a forum by then Secretary-General Kofi Annan at St. Gallen in late 2006.
  - Efforts by international actors (such as the ICRC's awareness-raising activities, the promotion of a voluntary code of conduct by the International Centre for Genetic Engineering and Biotechnology, and guidance provided by the WHO and UNCTAD) remain fragmented.
  - In contrast to some other proliferation concerns (e.g., in the area of nuclear weapons), there is no clear role for regionalized responses, except to the extent that regional organizations may help promote and implement global norms or control regimes.
- There is a clear need for a meaningful institutional setup to help promote and give teeth to the norm against biological weapons:
  - The absence of an international organization in support of the BTWC has a major impact on the ability to strengthen the norm against BW. There is lack of coordinated and sustained promotion of the convention, which has resulted in fewer state parties than the NPT or the CWC despite the fact that the BTWC has existed for over thirty years.
  - There is limited normative development and an absence of mechanisms to organize international cooperation for peaceful purposes among state parties. Furthermore, there is no international institutional partner to engage the scientific and industrial communities in norm- and regime-building.
  - One of the primary reasons to have a permanent institutional setup is to organize transparency with regard to relevant activities in order to reduce suspicions, in much the same way

that the IAEA's facilitation of information sharing and its own bilateral efforts with states parties build transparency and trust

- In addition, the creation of a more robust institutional capacity at the international level could help facilitate responses by the international community to biosecurity crises.
  - The involvement of such an organ might help avoid the involvement of the UN Security Council in the first place.
  - The modalities of how the Security Council would actually respond in the case of a reference under the BTWC have received little discussion. It is not clear how member states could bring their own expertise reliably and securely to bear, absent cooperation from an international institutional counterpart.
- It is, however, presently unclear where any more robust global institutional implementation capacity ought be situated.
  - There are a number of locations that are already home to institutions with relevant related expertise and mandates: Geneva (WHO/BTWC), The Hague (OPCW), Vienna (IAEA, UNODC), Paris (OIE), and Rome (FAO).
- It also remains unclear to what extent the UN may or ought be able to encourage industry self-regulation:
  - Could the UN use its convening power and its moral authority to encourage or even facilitate the development of industry-based, or even broader, control norms and implementation regimes?

4. What strategy is needed to achieve these renovations?

- The area of biosecurity may provide an important opportunity for the UN to demonstrate its potential to add value in responding to transnational security challenges:
  - States and private actors are increasingly calling for a coordinated global approach that highlights the synergies between biosecurity and development;
  - States also increasingly recognize the need for arrangements that draw in nonstate actors in both norm development and

implementation;

- But the mobilization of political will and implementation arrangements for such a purpose may be very complicated.

- Any strategy for mitigating the risks associated with biotechnology must give a role not only to the traditional security sector, but also to public health, agriculture, law enforcement, and education sectors, as well as the international scientific community and commercial industry. In short, it needs to be a multiple-stakeholder strategy.
- Whether or not the UN were to provide the roof for such an approach, the UN could help generate the initial political momentum for such a strategy by, for example, holding a conference on biosecurity, drawing in governments, industry, academia, and civil-society organizations.
  - This kind of political process is needed to develop a common frame of reference that provides the basis for treating the disease, state-originated, and nonstate misuse aspects of the biosecurity challenge, including the relationship between biotech proliferation and development.
- There is a need to both encourage and rethink current approaches to transparency enhancement and verification.
  - Sustained and concerted efforts need to be made in order to foster transparency-enhancing mechanisms at local, regional, and global levels. These strategies need to involve not only states but also nonstate and private actors and scientific communities.
  - There is a need to reframe and depoliticize the concept of verification, by presenting it as "transparency enhancing mechanisms," rather than as a concept of restrictions and limitations.
  - Effective strategies for verification must take into account the role of market forces and economic competition in biotechnology and the pharmaceutical industry. In order to integrate mechanisms of verification incentive structures need to be put in place.
- Independent thinking on means of verifying the BTWC should be stimulated:

- The absence of any meaningful tools for state parties to ascertain that other state parties are compliant is one of the BTWC's greatest weaknesses.
- Verification concepts are still very much rooted in Cold War thinking. Initiatives should be undertaken to stimulate independent and out-of-the-box thinking about the future meaning of verification. These insights should then be applied to the concrete case of biology and biotechnology, taking into consideration its unique characteristics in order to balance scientific and commercial interests with necessary and realistic security requirements.

- Although the Geneva Protocol and the BTWC are not UN treaties, there is a role for the UN to play by providing a forum to bring together all the relevant state and nonstate stakeholders to develop common frameworks.

IPI

Annex 3: Methodology and Timeline

Four questions guided the Task Forces in helping IPI to generate policy and institutional ideas for action:

1. What are the current policy and institutional shortcomings in multilateral security capacity on these issues?
2. Why have previous attempts to address these shortcomings failed?
3. What policies and institutional renovations, including legal frameworks and financial arrangements, are needed?
4. What strategy is needed to achieve these renovations?

The Opening Symposium on Development, Resources, and Environment served as an essential backdrop to the Task Forces. By examining these critical related issues, the symposium provided a larger geopolitical and economic context for the work of the subsequent Task Forces on security challenges. The two Task Forces, convened sequentially, addressed two thematic clusters of issues, each of which were broken down into smaller roundtables, as follows:

Task Force One	**Transnational Security Challenges** 1. Transnational Organized Crime 2. Weapons of Mass Destruction 3. Global Terrorism 4. Small Arms and Light Weapons 5. Biosecurity
Task Force Two	**Inter- and Intra-state Armed Conflict** 6. Peace Operations 7. Mediation and Peace Processes 8. Peacebuilding 9. Conflict Prevention and the Responsibility to Protect

Each Task Force consisted of members drawn from UN member states, academia, and policy-research institutions. The composition of each group ensured a broad range of perspectives regarding multilateral security capacity on the issues in question. Through this intensive work process, the Task Forces constituted core groups of stakeholders with an interest in developing practical strategies for addressing the institutional and policy shortcomings in these areas.

Task Force members met in opening and closing plenary sessions, as indicated below. Experts, in collaboration with IPI, prepared a series of non-papers, serving as a basis for discussion. Smaller groups gathered between the plenary sessions in roundtables, along with invited guest experts, for more in-depth, topic-specific discussions. Following each roundtable IPI produced a summary reflecting the group's discussions that served as a guide for the closing plenary session. Likewise, IPI drew on the Task Force deliberations to produce the final reports, detailing practical and achievable steps for strengthening multilateral action in the area in question. As noted, the content of these reports is the responsibility of IPI, and does not necessarily represent the positions or opinions of individual Task Force participants.

TIMELINE

Opening Symposium "Development, Resources, and Environment: Defining Challenges for the Security Agenda"
February 7-8, 2008 [Greentree Estate, Long Island]

Task Force One: Transnational Security Challenges

Opening Plenary Meeting
April 2-4, 2008 [Greentree Estate, Long Island]

1. Roundtable on **Transnational Organized Crime**
   April 10-11, 2008 [Millennium UN Plaza Hotel, New York]
2. Roundtable on **Weapons of Mass Destruction**
   April 24-25, 2008 [IPI, New York]

3. Roundtable on **Global Terrorism**
   May 1-2, 2008 [IPI, New York]

4. Roundtable on **Small Arms and Light Weapons**
   May 8-9, 2008 [Millennium UN Plaza Hotel, New York]

5. Roundtable on **Biosecurity**
   May 21-22, 2008 [IPI, New York]

Closing Plenary Meeting
May 28-30, 2008 [Greentree Estate, Long Island]

Task Force Two: Inter- and Intra-state Armed Conflict

Opening Plenary Meeting
June 11-12, 2008 [Greentree Estate, Long Island]

6. Roundtable on **Peace Operations**
   June 16-17, 2008 [IPI, New York]

7. Roundtable on **Mediation and Peace Processes**
   June 30-July 1, 2008 [IPI, New York]

8. Roundtable on **Peacebuilding**
   July 2-3, 2008 [IPI, New York]

9. Roundtable on **Conflict Prevention and the Responsibility to Protect**
   July 8-9, 2008 [IPI, New York]

Closing Plenary Meeting
October 15-16, 2008 [Greentree Estate, Long Island]

Annex 4: Task Force Participants

Co-Chairs

H.E. Mr. Abdullah M. Alsaidi, *Permanent Representative of the Republic of Yemen to the United Nations*

H.E. Mr. Dumisani Shadrack Kumalo, *Permanent Representative of the Republic of South Africa to the United Nations*

H.E. Mr. Claude Heller, *Permanent Representative of Mexico to the United Nations*

H.E. Mr. Peter Maurer, *Permanent Representative of Switzerland to the United Nations*

H.E. Mr. John McNee, *Permanent Representative of Canada to the United Nations*

H.E. Mr. Vanu Gopala Menon, *Permanent Representative of the Republic of Singapore to the United Nations*

H.E. Mr. Heraldo Muñoz, *Permanent Representative of Chile to the United Nations*

H.E. R.M. Marty M. Natalegawa, *Permanent Representative of the Republic of Indonesia to the United Nations*

H.E. Mr. Christian Wenaweser, *Permanent Representative of the Principality of Liechtenstein to the United Nations*

Permanent Missions and Delegations to the United Nations

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Argentina
Australia
Austria
Bangladesh
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Greece
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Indonesia
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Lithuania
Luxembourg
Malaysia
Mexico
Morocco
Mozambique
Netherlands
New Zealand
Niger
Nigeria
Norway
Pakistan
Palau
Portugal
Qatar
Republic of Korea
Romania
Russian Federation
Singapore
Slovak Republic
South Africa
Spain
Sweden
Switzerland
Tanzania
Turkey
Uganda
United Kingdom
United States of America
Uruguay
Viet Nam
Yemen

Expert Moderators and Contributors

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Task Force One on Transnational Security Challenges

Transnational Organized Crime

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Weapons of Mass Destruction

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Task Force Two on Inter- and Intra-state Armed Conflict

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