Appendix 14A. Enhancing bio-security: the need for a global strategy

ROGER ROFFEY and FRIDA KUHLAU

I. Introduction

In order to prevent the spread of biological weapon programmes from countries where they previously existed and to prevent terrorists from acquiring biological agents, materials and know-how, so-called threat reduction activities have been undertaken that include eliminating biological weapon-relevant equipment and infrastructure and redirecting the efforts of former weapon scientists to peaceful activities. One important aim of these activities has been to enhance safety when working with pathogens (bio-safety); another is to improve security at facilities where such work is carried out in order to preclude unauthorized access to agents, materials and knowledge (bio-security). Emerging and re-emerging diseases pose a threat to humankind, and global bio-security measures are an essential element of the efforts to decrease the risk of the use of biological agents for bio-terrorism.

Section II of this appendix discusses the increased perceived threat of bioterrorism, which has led to enhanced international awareness of the need to improve bio-security worldwide at facilities that deal with dangerous pathogens. Proposals to develop international standards or guidelines for bio-security are also addressed. Section III presents the concept of bio-security and the measures required to achieve adequate laboratory bio-security. Section IV describes the global risks of natural or deliberately induced outbreaks of infectious diseases and the need for a global, coordinated strategy of preventive measures, such as enhancing bio-safety and bio-security. Section V outlines the challenges presented by the proliferation of biological weapons, related materials and know-how and notes the current shift in threat reduc-

1 For approximately 10 years the United States has provided the main funding for threat reduction programmes which have covered the biological area and which have focused on Russia and the other former Soviet states. Recently, other Western countries have initiated projects in this area. Such support has, however, focused on biological research and redirecting the efforts of former weapon scientists to peaceful activities through assistance channelled via the international science and technology centres in Moscow and Kyiv. See International Science and Technology Center, Moscow, URL <http://www.istc.ru/>; and Science and Technology Center, Kyiv, URL <http://www.stcu.int/>. On threat reduction activities see Roffey, R., ‘From bio threat reduction to cooperation in biological proliferation prevention’, and Kuhlau, F., ‘From bio threat reduction to cooperation in biological proliferation prevention: overview of ongoing international activities aimed towards preventing proliferation of biological technology, material and expertise that may be used for hostile purposes’, Papers presented at the Conference on Strengthening European Action on WMD Non-proliferation and Disarmament: How Can Community Instruments Contribute?, Brussels, 7–8 Dec. 2005, URL <http://www.sipri.org/contents/expcon/euppconfmaterials.html>.

2 An emerging infectious disease is either a newly recognised, clinically distinct infectious disease, or a known disease whose reported incidence within the past two decades is increasing in a given place or among a specific population.’ British Health Protection Agency, CDR Weekly: The Communicable Disease Report Weekly, vol. 15, no. 6 (10 Feb. 2005), URL <http://www.hpa.org.uk/cdr/archives/2005/cdr0605.pdf>. Re-emerging diseases are those infections that have reappeared after a significant decrease in incidence.
tion activities towards taking a wider geographical approach and towards measures that address the prevention of bio-terrorism. The public health and environmental aspects of bio-security are also discussed. The conclusions are presented in section VI.

II. The increased perceived risk of bio-terrorism and enhanced international bio-security awareness

In the 1990s the issues of the proliferation of biological weapons and the threat of bio-terrorism became the focus of international attention for a number of reasons, including the discovery of Iraq’s biological weapon programme, revelations about the massive offensive biological weapon programme of the Soviet Union and the perceived increased threat of bio-terrorism. Recent incidents have illustrated the threat that terrorism poses to international peace and security. Another important factor in this context has been the rapid progress in biotechnology. If misused to develop more efficient biological weapons, biotechnology could become a driving force in promoting biological weapon programmes by creating new possibilities for future, potential military applications. An analysis of potential threats from the present to 2020 indicates that most terrorists will continue to use primarily conventional methods, but there is concern that smaller, well-informed terrorist groups might use biological agents to cause mass casualties. The risk of bio-terrorism cannot be disregarded, although it is difficult to identify which groups could and would use bio-terrorism and what would be the most likely targets.

The World Health Organization (WHO) has expressed serious concern about the threat to civilian populations presented by the deliberate use of biological, chemical or radiological agents, including via the contamination of food. The WHO has requested that its director-general provide tools and support to the WHO member states, in particular developing countries, in order to strengthen their national response systems.

5 These incidents include the 11 Sep. 2001 terrorist attacks on the USA and other terrorist incidents causing mass casualties (e.g., in Bali, in Oct. 2002; in Madrid, in Mar. 2004; in Beslan, Russia, in Sep. 2004; and in London, in July 2005).
The 2004 Report of the United Nations (UN) High-level Panel on Threats, Challenges and Change stressed that future biological threats and bio-security are key security concerns. Improving global disease-monitoring capabilities may be a means to counter new, emerging infectious diseases; defend against the threat of biological terrorism; and build effective and responsible states. The report calls on the states parties to the 1972 Biological and Toxin Weapons Convention (BTWC) to resume the negotiation of a credible verification protocol and to initiate negotiations on a new bio-security protocol. The report also draws attention to the overall deterioration of the global health system, and it highlights both the promise and the peril of the advances in biotechnology.

The 2003 BTWC Meeting of Experts discussed bio-safety and bio-security issues, and the parties acknowledged the need for risk assessment as a tool for designing appropriate and balanced legislation. They also noted that self-regulation of bio-security by facilities, including those for research or production, was unlikely to be adequate and that formal, governmental oversight arrangements, including legislation, would probably be necessary. The key elements of national bio-security programmes emerged from the discussions, and it was recognized that some states are more vulnerable to unauthorized access to facilities that possess dangerous pathogens owing to the lack of appropriate legislation and security. The meeting noted that only a small number of countries have enacted legislation that specifically addresses bio-security. There was, however, no common understanding or recommendation on how to proceed on this issue because of the current lack of political agreement about specific efforts to strengthen the BTWC.

**Developing bio-security standards**

Proposals have also been made to develop international bio-security standards or agree a legal protocol in order to prevent proliferators and terrorists from acquiring biological warfare agents and know-how and in order to simplify the tracing of agents used in bio-terrorism attacks. Such an approach could include legal commitments by states, a set of universal standards and an oversight mechanism. It could also comprise emergency response plans in the event of bio-security breaches; a mechanism for accounting and controlling pathogens and toxins when storing, using or transfer-

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11 United Nations (note 10), para. 27, p. 102, and para. 137, pp. 45–46. On the BTWC see chapter 14 and annex A in this volume.


13 In the final document of the 2002 Fifth Review Conference of the BTWC the states parties agreed to hold 3 annual meetings before the Sixth Review Conference in 2006 in order to discuss and promote common and effective action on a variety of subjects. Each meeting of the states parties was to be preceded by a 2-week preparatory Meeting of Experts, which would prepare factual reports describing their work. BTWC website, URL <http://www.opbw.org/new_process/new.htm>. See also chapter 14.

ring them; registration and licensing of facilities and personnel working with dangerous pathogens; and physical security measures. Negotiated global bio-security standards would reduce threats while reinforcing the legal prohibitions of the BTWC. It has been suggested that such a regime should include transparency measures for national bio-defence programmes and for the transfer of technology to developing countries in order to enhance their levels of bio-safety and bio-security. This regime should be incorporated into the framework of the BTWC and include the active participation of the scientific and public health organizations, such as the WHO, the UN Food and Agriculture Organization (FAO) and the World Organization for Animal Health (Office International des Epizooties, OIE).

III. The concept of bio-security

An effective strategy for biological security will differ significantly from corresponding strategies to curtail the spread of chemical or nuclear weapons. Bio-security not only is a matter of physical security, but also includes all the measures necessary to raise awareness of the risks involved and the measures to keep know-how, technology and dangerous pathogens or toxins from falling into the hands of those who would use them for criminal acts such as bio-terrorism or biological warfare. The concept of bio-security is relatively new, however, which explains why there is still no generally accepted definition.

A bio-security system should include elements of preparedness and response in the event of bio-safety or bio-security breaches. An essential part of a bio-security system is a programme of epidemiological surveillance that is effective, responds rapidly and is carried out at the local, regional and national levels of a state. This is crucial in order to enable early detection of possible releases of biological agents. Directly connected to this requirement is the ability to quickly identify potential disease-causing pathogens using rapid, reliable, standardized and internationally accepted diagnostic methods that enable confirmation of suspected cases of infectious disease outbreaks, identification of breaches of bio-safety or bio-security and characterization of the agent involved. Enforceable national legislation and regulations that cover the relevant areas are also essential. ‘Bio-security’ is sometimes inappropriately used to refer to a broader range of measures to prevent and respond to possible biological attacks (e.g., bio-defence, public health and law enforcement). Some bio-security measures overlap with policies on bio-safety, food safety, agricultural security, biodiversity and counter-terrorism measures. In the United States, for example, the term bio-security is used to motivate increased funding for bio-defence research, thereby draining resources from public health research. Such a broad definition of bio-security is inappropriate and should be avoided.


States interpret the term ‘bio-security’ in different ways, which complicates attempts to agree on terminology. E.g., in Australia and New Zealand bio-security refers to measures to protect agriculture from the risks posed by imported pests. In Russian there is no word for bio-security; only the term bio-safety is used, with its meaning dependent on the context.
Bio-security affects the international community, governments, industries and laboratories as well as individuals, and guidelines are badly needed. The WHO and other relevant international organizations have begun to define the concept of bio-security and to develop standards and guidelines for laboratories and production facilities. According to the draft WHO definition, laboratory bio-security refers to institutional and personal security measures adopted in laboratories that are designed to prevent unauthorized access to and the loss, theft, misuse, diversion or intentional release of valuable biological materials, thereby increasing their protection and accountability.\(^{17}\)

Laboratory bio-security is primarily achieved through ‘administrative and procedural requirements that clearly identify the threats to be addressed, the materials to be protected, the responsibilities of workers and the measures that restrict access to these materials by unauthorized individuals’.\(^{18}\) Bio-security practices should be a logical extension of good laboratory bio-safety procedures and good management practices. Laboratory bio-security and bio-safety are both essential to good laboratory practice. The WHO defines laboratory bio-safety as the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens or their accidental release as well as the containment of pathogens in a limited space or area. High levels of laboratory bio-safety can be achieved through the implementation of various laboratory measures that increase containment, thereby safeguarding workers, biological material and the environment.\(^{19}\) The WHO has urged its member states to promote improved bio-safety at laboratories.\(^{20}\)

Bio-safety measures should be integrated with bio-security as a component of the overall improvement of proliferation prevention measures. Thousands of production facilities and laboratories around the world carry out work involving dangerous pathogens or toxins. It is not known how many or which of these pathogens or toxins could be of potential interest to states or non-state actors (i.e., terrorists) who wish to acquire a biological weapon capability. In many cases, these facilities and research centres are aware of the need for bio-safety measures to protect their personnel and to prevent accidental releases. However, they are usually unaccustomed to considering the need for enhanced security measures on site. Often such measures are perceived by scientists as ineffective, intrusive, too costly or as an obstruction to free research, which has created scepticism about their value.

**The need for laboratory and facility bio-security**

Essential to the concept of bio-security is a system of laboratory bio-security that includes components such as risk assessment, physical security, personnel manage-

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\(^{17}\) According to their owners, users or those who retain them, valuable biological materials are biological materials that require administrative oversight and specific protective, monitoring and tracking measures. Valuable biological materials can include pathogens and toxins as well as culture collections, vaccine strains, food and genetically modified organisms, cell components, genetic elements, etc. World Health Organization (WHO), Department of Communicable Disease Surveillance and Response, ‘Laboratory biosecurity: WHO guidance’, WHO document WHO/CDS/CRS/LYO, Draft 9, 2005; and WHO official, Communication with Roffey, 15 Dec. 2005.


ment, control and handling of dangerous pathogens and toxins, the secure transfer of infectious materials between facilities, internal and cross-border accountability, information security, licensing and accreditation, programme management, scientific oversight, and well-developed standards and codes of practice.\textsuperscript{21} Bio-security is also promoted by instituting a culture of responsibility and accountability among those handling, using, transporting and overseeing work with dangerous pathogens and other valuable biological materials.

\textit{Assessing the risk}

The approaches to handling biological material differ for human, animal and plant pathogens and for toxins. Standards and procedures for the safe and secure storage, transfer, handling and disposal of dangerous pathogens should be developed by each facility. Identifying risks and listing the assets which the security system should protect based on plausible threat scenarios would facilitate this process.\textsuperscript{22} The classification of risk should be based on the type of asset in need of protection. The highest classification level should be assigned to material whose misuse would have national or international security consequences. When making such a classification, risk factors such as the probability of terrorist use should be considered together with the possible consequences of such use.\textsuperscript{23} The category of risk that an agent represents will not necessarily correspond to its bio-safety risk level. Most microbiological agents would be evaluated as posing minimal security risk.

\textit{Management and control}

The obvious approaches to physical security would be to install video cameras for monitoring purposes and to erect a physical barrier around a facility in order to limit access to all or part of it to authorized personnel only, to detect unauthorized access and to respond to security breaches. It is important that the facility’s management carefully selects personnel and promotes a security culture that is based on shared perceptions about security and the conviction that the security measures taken or proposed are important.\textsuperscript{24} Security is vital as regards the access to and the handling of dangerous pathogens or toxins; and serious consideration should be given to the control, registration and licensing of facilities and of individuals working with or handling them.\textsuperscript{25}


Many states control the import and export as well as transfer within the country of dangerous human, animal or plant pathogens. In some cases, in order to further reduce risks, dangerous pathogens or toxins can only be transferred between approved or licensed facilities. Several internationally agreed standards regulate the transport of dangerous pathogens and toxins and include requirements for the containers and packaging used for such transport. The UN Model Regulations define suitable packaging that affords a level of safety appropriate to the degree of risk.26

**Codes of conduct and practice**

In conjunction with other bio-security measures, codes of conduct and practice for scientists and technicians can affect how current and future threats from the use of biological materials are handled. The advances and benefits of the rapid developments in biotechnology, including genetic engineering, are immense, but they can also pose risks when mistakes or misuse occur.27 Individual responsibility, an increased awareness of how research could be misused and a culture of integrity and responsibility—including through scientific oversight, peer review, pre-publication review and whistle-blowing mechanisms—could be important in this context.28 The Interacadey Panel on International Issues in 2005 issued a statement on bio-security that addresses five fundamental issues that should be taken into account when formulating codes of conduct for scientists: awareness, safety and security, education and information, accountability and oversight.29 ‘Codes of practice’ refers to practical guidance and advice on how to achieve a certain standard. Such codes are considered enforceable, in contrast to ‘codes of conduct’—which are often interpreted to be advisory and to apply to individuals only.30 A code of good manufacturing practice is, for example, already used in the pharmaceutical industry.31

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IV. Infectious diseases: a threat to health and security

Despite medical advances, communicable diseases are still major threats to human health in both the technologically advanced and in the developing regions of the world. Outbreaks of infectious diseases continue to have significant consequences for public health, agriculture and the global economy.\textsuperscript{32} Measures to reduce the global risks caused by accidental and deliberately induced outbreaks of infectious disease require a coordinated global strategy, and it is well known that it is extremely difficult initially to distinguish one kind of outbreak from the other.\textsuperscript{33} Many disease-control strategies focus on the response to an outbreak, but bio-safety and bio-security are preventive measures that counter risks before they lead to outbreaks of disease. Emerging and re-emerging infectious diseases are global problems and should be addressed by a global strategy. Of immediate concern are the infectious disease situation, the deficiencies of the epidemiological disease surveillance system and weaknesses in diagnostic abilities, preparedness and response capacities. Improving preparedness and enhancing global public health efforts on a broad scale are essential. A disease outbreak in one country can spread internationally in a matter of hours or days. Many experts believe that there is a risk of a new influenza pandemic that could kill millions of people.\textsuperscript{34} The consequences of an outbreak of infectious disease resulting from the deliberate use of a pathogenic micro-organism could be at least as damaging as naturally occurring infections, and possibly more so. The 2001 attacks in the USA using letters that were filled with dried anthrax spores had a relatively modest health impact, with 5 deaths among the 22 people exposed to the letters, but the attacks caused enormous social disruption and economic damage.\textsuperscript{35}

Disease caused by leaks and accidents: a lack of oversight

In recent years it has been increasingly recognized that bioscience facilities are potential sources from which terrorists could obtain pathogens and toxins or knowledge that could be misused to create weapons. Bio-security in the sense of preventing theft is therefore a relatively new issue that only some Western countries, including only a few European Union (EU) members, have begun to consider seriously. In December 2005 the EU listed as a priority the promotion through funding of the physical secur-


ity of laboratories in Ukraine and other countries. There are large numbers of laboratories in the world that possess dangerous pathogens or toxins or conduct work on them, but there are no data on exactly how many such laboratories exist because an international inventory has not been conducted. Few countries even have a national inventory. It is known, however, that about 1500 state-owned and commercial culture collections exist worldwide—in addition to culture collections of various types at universities, hospitals, laboratories or commercial companies which do not trade in agents. For instance, an inventory of laboratories disclosed that 160 000 laboratories in 152 countries possess poliovirus.

Leaks from laboratories and accidents involving the release of pathogens have already occurred. In 2004, in Boston, Massachusetts, scientists mistakenly worked with live tularaemia strains when they thought they were working on a harmless vaccine strain. The mistake was first detected when the scientists displayed influenza-like symptoms. It is also known that in Beijing, Singapore and Taipei the severe acute respiratory syndrome (SARS) virus leaked in four cases from laboratories, and a case of Ebola haemorrhagic fever infection occurred because of an accident at the State Research Centre of Virology and Biotechnology (Vector) in Koltsovo, Russia. In 2004 a laboratory in the USA accidentally sent out proficiency tests that included pandemic influenza virus to 3750 laboratories around the world and then urgently had to ask the laboratories to destroy the samples. It proved difficult to track down all the samples and some seemed to have gone missing. The mistake was not discovered until one month after the samples had been distributed, when a patient was mistakenly diagnosed as having influenza because of the contamination from the proficiency test kit samples.

There is no information on the scale of global transfers of dangerous pathogens or on the quantity of such pathogens that are transferred and not covered by current regulations. As far as can be determined from publicly available information, there are also few cases of theft or illicit transfer of dangerous pathogens. The means to detect illicit transfers across borders are few and the task is difficult since the small quantities that would be required in order to have an effect can be easily concealed.

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37 Tucker (note 25).


41 Walgate (note 40).

Naturally emerging infectious diseases: avian influenza

After the SARS epidemic in 2003, attention focused on avian influenza and the risk of pandemic influenza. The WHO has repeatedly warned of the rapid spread of avian influenza virus (H5N1). The EU has agreed new guidelines for surveillance and has called for intensified bio-security and other disease prevention and control measures. The first recorded case of avian influenza occurred in 1997 in Hong Kong. Since 2003 the virus has spread westward, reaching Turkey, of the 184 reported human cases, 103 had died from the virus as of 23 March 2006. The virus has also led to the death of around 140 million birds. Confirmed reported human cases of infection have been detected in eight countries: Azerbaijan, Cambodia, China, Indonesia, Iraq, Thailand, Turkey and Viet Nam. The EU has banned the import of chickens, other poultry and birds from 14 countries, and it has urged increased surveillance by member states. Experts agree that even a complete global ban on the import and export of poultry will only slow the spread of the virus, not stop it.

43 See Njuguna (note 32).
44 Avian influenza, commonly known as ‘bird flu’, is an infectious disease of birds caused by type A strains of the influenza virus. The disease occurs worldwide and all birds are thought to be more or less susceptible to infection. There are a number of avian strains of the virus and, apart from H5N1 (the most severe strain), the H9N2 and H7N7 strains have also caused cases of mild illness in humans. See World Health Organization, ‘Avian influenza’, Fact sheet, URL <http://www.who.int/mediacentre/factsheets/avian_influenza/en/>.
51 The countries affected by the ban are Cambodia, China, Croatia, Indonesia, Kazakhstan, North Korea, Laos, Malaysia, Pakistan, Romania, Russia, Thailand, Turkey and Viet Nam.
There are indications that the avian influenza virus currently is not easily transmitted from birds to humans. So far there is no evidence of human-to-human transmission of the virus. The fear among health officials is, however, that if the virus combines with the human influenza virus it may be highly infectious and lead to a global influenza pandemic. Recent publication of the complete sequence of the 1918 Spanish influenza virus has shown that it was an avian influenza virus strain that adapted to humans. The potential risks of publishing complete sequences of dangerous pathogens should not be ignored. By using this sequence, scientists have recreated the virus and studied its effects in mice. It has been demonstrated that only 10 amino acid changes in the polymerase proteins consistently differentiate the 1918 and subsequent human influenza virus sequences from avian influenza virus sequences. Notably, a number of the same changes have been found in the H5N1 virus.

In the EU it is estimated that 2–3 million deaths could occur in the event of a pandemic influenza epidemic. More than 40 million people died in the last three global pandemics, in 1918, 1957 and 1968. As of November 2005, approximately 120 (62 per cent) of the 194 WHO member states had preparedness plans for a pandemic or were drawing up such plans; this is an increase of more than 70 countries since May 2005. Preparedness for and the response to pandemic influenza were important issues for the Sixth Ministerial Meeting of the Global Health Security Initiative, held in November 2005. The EU has updated and revised its preparedness plans, and the WHO has presented its strategic approach. The European Commission and China hosted an international pledging conference on avian and human influenza in Beijing in 2006. The international community has pledged $1.9 billion,

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of which $260 million was pledged by the EU. A global influenza pandemic could result in severe economic losses, estimated at $550 billion for high-income countries alone. Concern about an influenza pandemic has led to international initiatives such as the proposal to initiate a global influenza vaccine programme by the Group of Eight (G8) industrialized nations and the establishment of a new International Partnership on Avian and Pandemic Influenza announced by US President George W. Bush. Twenty-seven countries possess stockpiles of anti-virus drugs in amounts sufficient to cover 2 per cent of the world’s population. Nine states produce most of the world’s vaccine. Europe’s production amounts to 70 per cent of the global total. There is great concern that, in an emergency, the states with vaccine production facilities will limit or ban exports to other states.

Other major infectious diseases: requests for international cooperation

Another major global threat from infectious disease is the spread of HIV/AIDS, which has killed more than 25 million people since 1981. Sub-Saharan Africa has been more severely affected by AIDS than any other part of the world. The UN has reported that 25.8 million adults and children are infected with HIV in the region, where about 10 per cent of the world’s population lives and where two-thirds of the total of HIV-infected people also live. AIDS has surpassed malaria as the leading cause of death in Africa, and it kills more Africans than conflict. In addition, and because of the HIV/AIDS epidemic, there are around 8.5 million diagnosed cases of tuberculosis, and 2 million people die of the disease every year. The HIV/AIDS epidemic is also growing in other regions in the world, particularly in Eastern Europe and Central Asia where the HIV-infected population has increased by one-quarter, to 1.6 million, since 2003 and the number of deaths almost doubled to 62,000. Another affected region is East Asia, where the number of infected people increased by


67 The states are Australia, Canada, France, Germany, Italy, Japan, the Netherlands, the UK and the USA.

68 Osterholm (note 55); and ‘Preparing for a pandemic: more vaccine is needed to prepare the world for an influenza pandemic’, The Economist, 22 Sep. 2005, p. 95.


70 Joint UN Programme on HIV/AIDS and the WHO (note 69), pp. 1–3.

one-fifth, to 870,000, between 2003 and 2005. The total number of HIV-infected people reached 40.3 million in 2005.72

Owing to lack of funding and resources, new strains of tuberculosis have developed that are more difficult to treat. The recent SARS outbreak illustrated how the spread of disease can be limited when states cooperate closely and with international institutions.73 UN agencies estimate that about $35 billion is needed to fight preventable diseases such as AIDS, malaria and tuberculosis, which together kill 2–3 million children every year.74 In addition, livestock agriculture is the most important industry in sub-Saharan Africa, and diseases are its biggest constraint. Crop diseases and pests pose major threats to Africa’s food security.75

V. International efforts to prevent biological weapon proliferation

Parallel to naturally occurring diseases and their sudden outbreaks, other major challenges and threats have emerged, such as the risk of the proliferation of biological weapons or the intentional use of disease by terrorists. The security measures required to address these threats should take into account the dual-use nature of biological materials and equipment, the small amounts of agent initially needed to cause an outbreak of disease, the relative ease with which such agents can be produced, their availability as the result of natural outbreaks and the dynamic nature of biotechnology.

The international community has attempted to prevent the proliferation of biological weapons, related materials and know-how but with limited success. Arms control and disarmament actions in the biological area have proved more difficult than for other weapon of mass destruction categories not only for political reasons, but also owing to practical factors such as the relative ease of acquiring dual-use materials and technologies. The obstacles to progress include the extreme secrecy surrounding work in biological weapon-related areas; the difficulty of identifying prohibited activities, especially by non-state actors; and the technical and political challenges of verifying that materials or activities are not being used for hostile purposes.76 Threat assessments and intelligence are crucial in order to monitor biological weapon capabilities, and the inherent limitation of intelligence information in this area was recently demonstrated again by the intelligence failure in Iraq.77

State contributions to enhance bio-security

Thus far most international bio-security-related activities have been carried out under the US threat reduction programmes in Russia and the other former Soviet states. The

72 Joint UN Programme on HIV/AIDS and the World Health Organization (note 69).
76 Roffey (note 6).
changed international security environment has resulted in the need for broader non-proliferation and disarmament activities that are intended to deal with global problems such as the risks posed by bio-terrorism and outbreaks of infectious diseases. The focus of activities has moved from threat reduction to terrorism prevention, public health-related issues and environmental protection. These changes raise the question of whether there is a need to further modify current threat reduction approaches. Support should be refocused from the nuclear to the biological area and expanded beyond the former Soviet Union.

Compared to the budgets for assistance in, for example, the nuclear field, the contribution to improving bio-security is minimal. The USA is by far the largest contributor in the biological area: its annual funding is estimated to be approximately $90–100 million, although most of the funding is not allocated to bio-security. Other states contribute mainly through the G8 Global Partnership against the Spread of Weapons of Mass Destruction or, in the case of the EU member states, through the Technical Assistance to the Commonwealth of Independent States (TACIS) programme. These contributions primarily fund the science centres in Russia and Ukraine that were established to engage former Soviet weapon scientists in peaceful research. The funding for bio-security enhancement is limited in the former Soviet states. However, states such as Canada, France and the United Kingdom are becoming increasingly involved in bio-security-related activities there.

### New international approaches to prevent biological proliferation

The BTWC is the natural framework in which bio-security issues could be developed and agreed upon in a multilateral setting, but since the negotiations on a verification protocol for the treaty stalled in 2001 little has been achieved. The lack of a concrete outcome from the discussions in the BTWC framework has spurred a range of activities designed to promote bio-security in organizations such as the Organisation for Economic Co-operation and Development (OECD) and the WHO and among non-governmental organizations. These organizations play important roles in developing the concept of bio-security, in raising global awareness of the issues involved and in highlighting the need to engage various actors to prevent proliferation. Lack of coordination of these initiatives, however, has made it difficult to harmonize bio-security measures, and their impact has been limited so far.

The International Science and Technology Center (ISTC) in Moscow and the Science and Technology Center (STCU) in Kyiv play central roles in promoting non-proliferation in the former Soviet Union by facilitating cooperation between scientists

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80 Roffey (note 1); and Kuhlau (note 1).
81 The states that are involved in significant bio-security support activities are Canada, Finland, France, Sweden, the UK and the USA.
82 International Science and Technology Center (note 1); and Science and Technology Center (note 1).
and Western states.\textsuperscript{84} Other international organizations such as the FAO, the OECD, the OIE and the WHO act from their different perspectives to enhance bio-security through the development of guidelines, standards and principles.\textsuperscript{85} The WHO has also taken action to help its member states improve their preparedness against bio-terrorism.\textsuperscript{86} The World Bank continues to support the improvement of epidemiological surveillance systems and the development of medical countermeasures and ways to handle disease outbreaks.\textsuperscript{87} The OECD is also actively pursuing the establishment of a global network of biological resource centres (BRCs), which will operate as focal points and serve as repositories to permit the safe and secure exchange of microbial cultures among its members.\textsuperscript{88} The national centres will have the key function of safeguarding valuable culture collections for the life sciences and the biotechnology industry and will provide global coordination in the form of a BRC network to increase efficiency and transparency and to facilitate the international exchange of these cultures in a safe and secure manner.\textsuperscript{89}

As noted, the G8 Global Partnership has played an important role in addressing non-proliferation, disarmament and counter-terrorism issues with a focus on the former Soviet Union.\textsuperscript{90} However, the funding committed and allocated for the biological area is minimal and the contributions pledged by some states in the G8 framework have not yet been honoured.\textsuperscript{91} Another partnership, the Global Health Security Initiative, includes the G7 states plus the European Commission and Mexico.\textsuperscript{92} It aims to improve global health security and meet the threats of chemical, biological, radiological and nuclear terrorism as well as pandemic influenza.\textsuperscript{93} In the biological field, its goals are to build joint surveillance networks, to develop approaches for enhancing national and international preparedness, to prepare the response to outbreaks of disease and to strengthen public health emergency response and detection.\textsuperscript{94} It also aims to achieve common standards and promote cooperation among labora-

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  \item \textsuperscript{84} International Science and Technology Center (note 1); and Science and Technology Center (note 1).
  \item \textsuperscript{85} Roffey (note 1); and Kuhlau (note 1).
  \item \textsuperscript{86} World Health Organization (WHO), \textit{Public Health Response to Biological and Chemical Weapons: \textit{WHO Guidance} (WHO: Geneva, 2004).}
  \item \textsuperscript{89} Organisation for Economic Co-operation and Development (note 88); and Tucker (note 25).
  \item \textsuperscript{90} Reports from G8 summit meetings are available at URL <http://www.g8.gov.uk/>. The members of the G8 are listed in the glossary in this volume.
  \item \textsuperscript{91} In addition to the G8, 13 states—Australia, Belgium, the Czech Republic, Denmark, Finland, Ireland, South Korea, the Netherlands, New Zealand, Norway, Poland, Sweden and Switzerland—joined the Global Partnership in 2003–2004. The EU is also a member.
  \item \textsuperscript{92} The G7 states are Canada, France, Germany, Italy, Japan, the UK and the USA. The European Commission and Mexico participate in the Global Health Security Initiative.
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and the Global Health Security Action Group has been created to improve linkages between laboratories.\textsuperscript{96}

\section*{Challenges to current non-proliferation approaches}

The non-proliferation approach has so far focused on threat reduction activities, but such activities have had a limited focus on biological issues in general and bio-security in particular. After a decade of assistance in Russia and the other former Soviet states, new geographical regions, such as Africa and parts of Asia, should also be prioritized. Proliferation risks are high in these regions and concern exists with regard to their potential as favourable environments for terrorists seeking to acquire biological agents and develop biological weapon capabilities. In order to prevent proliferation and enhance bio-security in these regions, it is necessary to rethink non-proliferation approaches. In most African states, bio-security, or even bio-safety, would be considered a luxury and is given lower priority than basic needs such as secure access to food and water and combating infectious diseases. A new approach is needed in order to prevent proliferation and improve the level of bio-security. The urgent need to strengthen the public health infrastructure can be used to make the case for also increasing bio-safety and bio-security in order to combat disease. A well-coordinated and well-developed international strategy is needed to assist primarily Africa, but also parts of Asia, to cope with threats to health and security by putting in place efficient epidemiological surveillance systems, diagnostic capabilities and crucial bio-security components for laboratories and facilities that deal with dangerous pathogens and toxins. Such a strategy would also increase the control of pathogens and the awareness of which pathogens exist and would enhance preparedness and the response to naturally occurring diseases as well as those deliberately induced. The public health approach would be useful as a point of entry in other regions of the world as well.

The first meeting to deal with bio-terrorism and bio-security issues in sub-Saharan Africa was held in Kampala, Uganda, in September 2005. Ideas for an African initiative for a Global Bargain on Bio-security and Bioscience were developed that will be presented to the African Union (AU) if there is adequate support. In order to promote human security and protect against misuse of the biological sciences, the African states would make certain commitments—including in the area of enhancing bio-security—in exchange for assistance in a number of areas such as public health infrastructure and capacities; development programmes for vaccines and other capabilities to protect against diseases like AIDS, malaria and tuberculosis; disease monitoring; notification and surveillance systems; and strengthening African universities. The AU has also identified terrorism as a priority and has established the Centre for the Study of and Research on Terrorism, in Algiers.\textsuperscript{97} The potential use of biological agents might have more serious consequences in Africa than in other parts of the world because large parts of the population have a decreased immune defence

\textsuperscript{96} G7 health ministers, ‘Statement of G7 health ministers’ meeting’, Ottawa, 7 Nov. 2001, URL \texttt{<http://www.g8.utoronto.ca/health/ottawa2001.html>}.  
owing to HIV infection. In addition, the public health infrastructure is weak, and there is a lack of medicines and other essential items.

VI. Conclusions: general bio-security trends

In the past decade the world has confronted new biological challenges because of a combination of emerging and re-emerging infectious diseases, rapid advances in biotechnology and a perceived increased bio-terrorism threat. It is now also generally accepted that security measures to prevent proliferation and bio-terrorism are needed in the biological field. The current limited international approach of enhancing bio-safety and bio-security through measures developed under the threat reduction umbrella has prevailed for a decade in assistance programmes in the former Soviet Union. Bio-security has to be seriously considered when developing a broader approach to the new global threats. Current methods, approaches and ways of carrying out support programmes demand modification to address the changing global security environment and the increased awareness of other geographical regions of concern.

Recent outbreaks of infectious disease have highlighted the global challenge they present. Emerging and re-emerging infectious diseases have developed from being merely public health and foreign aid issues to a prioritized issue on the global security agenda. The security implications of disease have become the focus of attention because diseases such as AIDS, malaria and tuberculosis have had devastating social, economic, health and security effects in many parts of the world, not least Africa, for a considerable period of time.

A well-coordinated international strategy for coping with the threats posed by disease outbreaks, whether naturally occurring or deliberately induced, should be developed, taking into account the need to prevent unauthorized access to dangerous pathogens and toxins. Global discussion of these issues is needed in order to achieve a well-balanced and realistic approach to them. Such an approach should be developed in a multilateral framework such as the BTWC in close cooperation with international organizations such as the FAO, the OECD, the OIE and the WHO. Prevention efforts will have limited practical effect unless there is a common international understanding of the problem and its global scale and of what assistance is required and where. Immediate steps could be taken to strengthen the public health infrastructure through well-focused aid programmes in regions like Africa where the immense scale of the need in this area is clear. The next step would be to enhance preparedness, oversight and the general level of biological security at facilities that deal with dangerous pathogens or toxins. Such work should also be concentrated at fewer facilities worldwide. By enhancing preparedness, control and transparency, particularly in regions of concern, the global ability to prevent proliferation in the biological area would increase and the ability to prevent and limit the spread of future infectious diseases would be enhanced.