From bio threat reduction to cooperation in biological proliferation prevention

Roger Roffey

sipri
Stockholm International Peace Research Institute

Background paper 4
Conference on Strengthening European Action on WMD Non-proliferation and Disarmament: How Can Community Instruments Contribute?, Brussels, 7–8 December 2005

Contents

Annexes

Frida Kuhlau

Acronyms and abbreviations

AG	Australia Group
BRC	Biological research centre
BTWC	Biological and Toxin Weapons Convention (1972)
BW	Biological weapon(s)biological warfare
CBR	Chemical, biological and radiological
CBRN	Chemical, biological, radiological and nuclear
CDC	Center for Disease Control (USA)
CSIS	Center for Strategic and International Studies
CTR	Cooperative threat reduction
CWC	Chemical Weapons Convention (1993)
DG	Directorate-General
DOD	Department of Defense (USA)
EC	European Community
ECDC	European Centre for Disease Prevention and Control
EU	European Union
EWRS	Early Warning and Response System
FAO	Food and Agriculture Organization of the United Nations
FSU	Former Soviet Union
G7	Group of Seven industrialized countries
G8	Group of Eight industrialized countries (the G7 plus Russia)
GHSAG	Global Health Security Action Group
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
INTAS	International Association for the Promotion of Co-operation with Scientists from the New Independent States of the Former Soviet Union
ISG	Iraq Survey Group
ISTC	International Science and Technology Centre (Moscow)
NBC	Nuclear, biological and chemical
NDCI	Non-proliferation and Disarmament Cooperation Initiative
NIS	Newly independent states
NTI	Nuclear Threat Initiative
OECD	Organisation for Economic Co-operation and Development
OIE	Office International des épizooties (World Organization for Animal Health)
OPCW	Organisation for the Prohibition of Chemical Weapons
R&D	Research and development
RANSAC	Russian–American Nuclear Security Advisory Council
SARS	Severe acute respiratory syndrome
STCU	Science and Technology Centre in Ukraine (Kiev)
UK	United Kingdom
UN	United Nations
UNSC	United Nations Security Council
WFCC	World Federation for Culture Collections
WHO	World Health Organization
WMD	Weapon(s) of mass destruction

Acknowledgements

In the course of this study valuable information and comments were received during visits and by mail for which I would like to express my thanks—not least for the mass of information and support provided from colleagues in the European Commission, the USA and Canada. Specific thanks to: Georgios Gouvras, Helmut Wallerius and Solveig Wallyn, European Commission, Directorate-General Health and Consumer Protection, Luxembourg; Barbara Rhode, European Commission, Multilateral Co-operation Activities; Marc Deffrennes, European Commission, Section for non-proliferation and disarmament; Andrew Weber, Adviser, US Department of Defense (DOD), Cooperative Threat Reduction Policy Office of the Secretary of Defense; Michael A. Balady, DOD Defense Threat Reduction Agency (DTRA) Biological Weapons Prevention Programme; Rozanne D. Oliver, Jason Rao, Don P. Bourque and Elisabeth E. Cameron, US Department of State, Office of Proliferation Threat Reduction, Bureau of Nonproliferation; Susanna Partridge, US Department of Health and Human Services (DHHS) Biological Engagement Programme; Melanie Petersen, US Department of Agriculture, Agricultural Research Service; Bill Freeman, US Environmental Protection Agency, Office of International Affairs; Stephanie Ghetti-Mirabello and Anne Phillips, US Department of Energy (DOE), Biological Programme Manager, National Nuclear Security Administration, Initiatives for Proliferation Prevention (IPP); Cathy Campbell, US Civilian Research and Development Foundation (CRDF); Kenneth N. Luongo, Raphael Della Ratta and William Hoehn, Russian American Nuclear Security Advisory Council (RANSAC); Leonard S. Spector; Jonathan B. Tucker and Sonia Ben Ouagrham, Center for Nonproliferation Studies, Monterey Institute of International Studies; Mark S. Smolinski, Biological Programmes, Nuclear Threat Initiative (NTI); Amy E. Smithson, Center for Strategic and International Studies (CSIS) International Security Programme; Cindy Vestergaard and Maureen Best, Chemical and Biological, Global Partnership Programme, Canadian Department of Foreign Affairs; Sue MacLaren, UK Ministry of Defence, Russian Assistance Programme, Proliferation and Arms Control Secretariat, DSTL Porton Down; Uwe Meyer, International Science and Technology Center (ISTC), Moscow; John Zimmerman, Science and Technology Center in Ukraine (STCU), Kiev; Timo Korpela, Finnish–Russian Joint Biotechnology Laboratory, Turku, Finland; Helmut Bachmayer, European Biosafety Association (EBSA); Vladimir A. Orlov, Geneva Centre for Security Policy (GCSP); Yuri Remnev, Center for Modern Medical Technology TEMPO, Moscow; and, last but not least, Frida Kuhlau at SIPRI who took part in the meetings, took notes and prepared a report on the ongoing threat reduction activities in the biological area; and John Hart at SIPRI for background information and a meeting in Moscow.

1. Introduction

The fact that biological agents can self-replicate means that bio-security measures will differ from those for the chemical and nuclear areas. For the biological area it will not be enough to focus only on the physical security of facilities. Thousands of facilities or laboratories around the world carry out work involving dangerous pathogens or toxins, although the exact number and locations are unknown. These facilities could be of interest to potential states or non-state actors that want to acquire a biological weapons (BW) or a bio-terrorist capability. In many cases these facilities and research centres are aware of the need for bio-safety measures to protect their own personnel and to prevent accidental releases. Usually, however, they are not yet accustomed to think about the need for enhanced security measures at facilities. Such measures are still often perceived as ineffective, intrusive and too costly, and there is a concern that they might well obstruct the freedom to conduct research. Many scientists are sceptical in general about their value. The concept of bio-security is fairly new—another partial explanation of why there is still no commonly accepted definition. Bio-security implies taking active measures to enhance and raise awareness of the risks of proliferation and to protect know-how and dangerous pathogens and toxins against theft or malicious diversion from facilities. The increased threat from bio-terrorism and the risk of proliferation of BW materials and know-how justifies improving control and oversight while at the same time keeping a realistic balance between security needs and the need to permit legitimate research.

This study aims to examine how European Union (EU) biological security assistance can be reinforced. The primary focus is on Russia and the independent former Soviet republics but other potential areas for non-proliferation assistance programmes are also considered.[1] The main focus will be on bio-security.

The study first defines bio-security in general, analysing information on the present biological threat reduction activities and bio-security risks in the former Soviet Union (FSU) and other potential areas. More detailed information describing recent and current threat reduction initiatives or non-proliferation prevention carried out or planned with a focus on limiting bio-security threats is presented in an annex. The main bio-security building approaches are described and discussed here, as are the potential obstacles to adopting these approaches. Based on this, conclusions and options are presented for potential European bio-security proliferation prevention initiatives.

For this study bio-security encompasses a broad range of measures to prevent and respond to possible deliberate release of biological agents due to theft or unauthorized acquisition of biological agents or materials, for example, by terrorists. It is connected with work at facilities or laboratories as well as the transfer of agents. 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 persons. One essential part of a bio-security system is a system of epidemiological surveillance that is effective, responds rapidly, and covers the local, regional and national levels in a country. This is important as it will make it possible detect intentional releases of biological agents or unintentional leakages, in addition to natural outbreaks of infectious diseases, at an early stage. Connected to this is the requirement for a

[1] This was one priority identified in the list of priorities for coherent implementation in Council of the European Union, 'Implementation of the WMD Strategy: Six-monthly progress report', Doc. 15246/04, Brussels, 3 Dec. 2004.

capacity to rapidly identify any potential disease using rapid, reliable, standardized and internationally accepted diagnostic methods in order to be able to confirm any suspected cases of infectious disease outbreaks or breaches of bio-security and to characterize the agent involved. It is important is to have modern and effective national legislation and regulations in all these areas and to ensure that they are enforced. To prevent proliferation from areas with previous BW programmes, BW-relevant equipment and infrastructure have sometimes been removed and former weapons scientists have been given the opportunity to work on peaceful projects.

In general biological threats, whatever their nature, should be seen as risks to be managed rather than problems to be solved. Bio-security concerns the international community, governments, industries and laboratories, as well as individuals. For some time now the World Health Organization (WHO) together with other relevant international organizations has been initiating work on developing guidelines for bio-security. The draft text of a definition has been developed and will be used for this study. Facility or laboratory bio-security as defined by the WHO refers to 'managerial, administrative, technical and physical measures designed to prevent the loss, theft and/or misuse of valuable biological materials'.[2] 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'. An effective bio-security programme should be based on risk management and should include many components, implemented in a graded manner to mitigate the identified risks.

Traditional security programmes generally focus on physical protection, which is most effective against external threats. Although physical security systems can detect entry by those without authorized access, other elements of a bio-security programme are also necessary to take into consideration threats from within the facility. A well-designed bio-security programme will include all the following elements: risk assessment, physical security, personnel management, scientific oversight, dangerous pathogen/toxin control and accountability, transport security, and information security.[3] Bio-security is facilitated by the establishment of a culture of responsibility and accountability among those who handle, use, store and oversee work with pathogens and other valuable biological materials.

Laboratory bio-security practices should be a logical extension of good laboratory bio-safety procedures and good management practices. A fundamental benefit of laboratory bio-security is the reduction of the risk of valuable biological materials being lost, subject to unauthorized access, stolen or used inappropriately. Laboratory bio-security and laboratory bio-safety are both essential to good laboratory practice. Bio-safety is defined as the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens or their accidental release.[4] The primary objective of both is to keep dangerous and valuable biological materials safe and secure inside the laboratory.

Laboratory bio-security relies, first and foremost, on sound laboratory bio-safety practices. The WHO defines 'laboratory bio-safety' as the containment principles, technologies, and practices that are implemented to prevent unintentional exposure to

[2] World Health Organization (WHO), Department of Communicable Disease Surveillance and Response, 'Laboratory biosecurity', WHO guidance, Draft 9, WHO/CDS/CRS/LYO, 2005.

[3] Chyba, C. F., 'Towards biological security', *Foreign Affairs*, May/June 2002, p 122.

[4] World Health Organization)WHO), *Laboratory Safety Manual*, 3rd edn (2004), WHO/CDS/CSR/LYO/2004.11, p. 47, <http://ww.who.int/entity/csr/resources/publications/biosafety/Biosafety7.pdf>.

pathogens or their accidental release as well as to keep pathogens within a limited space or area. Laboratory bio-safety is preventive in nature and seeks to reduce the unintentional exposure of workers and the environment to biological hazards. High levels of laboratory bio-safety can be achieved through the implementation of graded laboratory measures that increase containment, thereby safeguarding the worker, the biological material itself and the environment.[5]

The term bio-security is also sometimes used to refer to the much broader range of measures to prevent and respond to possible biological attacks (e.g. bio-defence, public health, law enforcement and so on). Some bio-security measures overlap with policies on bio-safety, agricultural security, biodiversity and counter-terrorism.[6]

The magnitude of the problem

The challenges posed by biological proliferation, the dual-use character of materials and equipment, the small amounts of agents initially needed, the relative ease with which they can be produced their availability from natural outbreaks and the dynamic nature of biotechnology, guarantee that an effective strategy for biological security will look very different from the corresponding techniques used to curtail the spread of nuclear or chemical weapons.

Biological security requires a different mix of measures for non-proliferation, deterrence and defence. During the 1990s the problems connected with the proliferation of biological weapons and risks with bio-terrorism received greater attention in the light of Iraq's BW programme, revelations of the massive Soviet offensive BW programme[7] and the perceived increased threat of bio-terrorism. To this can be added the terrorist attacks causing mass casualties in the USA in 2001 and Spain in 2004, which focused international attention on the fight against terrorism. Most terrorists will probably continue to use conventional techniques, but there is concern some groups might use biological agents in seeking to cause mass casualties. Terrorist use of biological agents is likely and the range of options available to them will grow.[8] The rapid progress in biotechnology and its potential for misuse to create more efficient BW could open new possibilities for future potential misuse.[9] According to Interpol, 'the evidence uncovered by law enforcement and concerns voiced at global, regional and national levels regarding the potential use of biological agents by terrorists to perpetrate a mass casualty attack demonstrate that we face a very real and present threat'.[10]

Over the past five years the perceived threat from BW and bio-terrorism has changed as a result of their actual use and the enhanced risk of mass-casualty transnational terrorism with the ambition to obtain weapons of mass destruction (WMD). On the basis of intelligence information mainly from the USA it has been assessed that some 10 states might be trying to acquire a BW capability. It is well known that it is

[5] WHO, *Laboratory Biosafety Manual*, 3rd edn (2004); and National Institutes of Health and Centers for Disease Control and Prevention, *Biosafety in Microbiological and Biomedical Laboratories*, 4th edn, May 1999, <http://bmbl.od.nih.gov/contents.htm>.

[6] Barletta, M., 'Biosecurity measures for preventing bioterrorism', Monterey Institute of International Studies, Center for Nonproliferation Studies, 27 Nov. 2002.

[7] Alibek, K., *Biohazard: The Chilling True Story of the Largest Bovert Biological Weapons Programme in the World – Told by the Man Who Ran It* (Random House: New York, 1999).

[8] National Intelligence Council, *Mapping the Global Future*, Report of the National Intelligence Council's 2020 Project, NIC-2004-13, Dec. 2004, p. 95, < http://www.cia.gov/nic/NIC_2020_project.html>.

[9] National Intelligence Council (note 8).

[10] Interpol Media Release, 1 Mar. 2005, <http://www.interpol.int/Public/ICPO/PressReleases/PR2005/PR200510.asp> (accessed 8 Mar. 2005).

extremely difficult to prevent the spread of BW capabilities due to the dual-use nature of the biotechnology area. Today the proliferation of WMD to states or non-state actors, know-how, technology and materials is a major threat that only international cooperation can prevent. The collapse of the Soviet Union with its large WMD legacy and the rise of a more active and global terrorism are of major concern. International cooperation is therefore essential. The leaders of the Group of Eight industrialized countries (G8) took an important step in the right direction at the Kananaskis summit in Canada in June 2002 by adopting a Global Partnership against the Spread of Weapons and Materials of Mass Destruction.

The international community has tried to prevent the proliferation of biological weapons, related materials and know-how but with so far somewhat limited progress. In 2001 the multilateral negotiations to strengthen the 1972 Biological and Toxin Weapons Convention (BTWC) with a verification mechanism collapsed. Arms control and disarmament actions in the biological area have been found to be more difficult than for other WMD categories, not least for political reasons, but also for practical reasons. One factor is the ease with which dual-use materials and technologies, as well as know-how, for small-scale production can be acquired. In addition there are the extreme secrecy that has always surrounded work in the BW area, the well-known difficulty of identifying prohibited activities, especially for non-state actors, and the technical as well as political challenges in being able to verify that materials or activities are not being used for hostile purposes. Threat assessment and intelligence are crucial in order to monitor the risks with BW, and recently the inherent limitations of intelligence information in this area have again been clearly demonstrated in the case of Iraq. A consequence of this is that there is no exact knowledge of current state or non-state activities in the biological area or even of which agents are being worked on, only suspicions and knowledgeable assumptions.

The changed international security environment has meant that the scope of non-proliferation and disarmament assistance should be widened beyond the focus on the former Soviet Union reflected in, for example, the original US Cooperative Threat Reduction (CTR) Program carried out by the US Department of Defense (DOD). The problems associated with bio-terrorism and outbreaks of infectious diseases are global and therefore threat reduction activities need to be supplemented by the prevention of terrorism, strengthened public health and environmental protection.[11] Many of the projects that are in the planning stage today are multi-functional, which is why financing them can sometimes become difficult due to bureaucratic problems and the difficulties of securing cooperation between agencies and ministries in donor countries that have no history of working together.

Communicable diseases are still major threats to human health and can threaten technologically advanced regions of the world, such as the USA and the European Union, as much as developing regions of the world with only limited health infrastructures. Measures to reduce risks due to accidental and deliberate outbreaks of infectious disease require a coordinated, national and global strategy. Many strategies to fight disease will focus on response to an outbreak, monitoring spread by disease surveillance, increasing the effectiveness and availability of therapeutics, improving diagnostic capabilities, and developing technologies to handle the consequences. Pre-

[11] An alternative expression, 'international non-proliferation and disarmament assistance' (INDA), has been suggested in Anthony, I., 'The role of the EU in international non-proliferation and disarmament assistance', Geneva Centre for Security Policy, Occasional Paper no. 44, Oct. 2004. The expression 'non-proliferation and disarmament cooperation' has been used in the title of the series of meetings organized under the Nonproliferation and Disarmament Cooperation Initiative (NDCI).

venting outbreaks before they occur should also be one objective of bio-security and bio-safety measures. The notion that technical and social development would eliminate the risk of outbreaks of disease has not been validated and new challenges have emerged due to the globalization of world society. New and re-emerging infectious diseases will continue to pose a rising global threat, and malaria, tuberculosis and HIV/AIDS alone still kill some 5 million people every year. At least 30 previously unknown diseases have appeared since 1973, including HIV/AIDS, Ebola fever, hepatitis C, severe acute respiratory syndrome (SARS)and Nipah, for which no cures are available yet. In addition, other diseases such as measles, influenza and the threat of pandemic 'flu are serious health problems on a global scale.[12]

In the foreword of the United Nations (UN) High Level Report the Secretary-General points out bio-security concerns and the deterioration of our global health system, and highlights both the promise and the peril of advances in biotechnology. There is a vision of collective security, one that addresses all the major threats to international security felt around the world where the security of the most affluent state can be held hostage to the ability of the poorest state to contain an emerging disease. Every threat to international security today enlarges the risk of other threats.[13] Bio-security as a phenomenon in a wide sense has become a key security issues in this century[14] and the BTWC 'new process' bio-security was one topic for discussion during the 2004 expert meeting in Geneva. Other groups such as the G7+ Global Health Security Action Group (GHSAG), the Global Partnership, the Organisation for Economic Co-operation and Development (OECD), and the EU have all taken initiatives in this area. The global problem of new or emerging diseases have been noted.

To this can be added that in the agricultural sector bio-security means managing all biological and environmental risks associated with food and agriculture, including forestry and fisheries. The need for bio-security intensifies with economic globalization, rapid improvements in communications, transport, trade, technological progress, and increased awareness of the importance of biodiversity.

Limitations of the study

The very short time available for this study has imposed a number of limitations. It has not been possible to collect or evaluate all the many projects that have been carried out over the years as part of states' threat reduction programmes. Instead recent projects have been grouped in broad categories based on the general aim of the projects to give a picture of the types of research that has been funded. This material is presented in the annex to this report and analysed here with a focus on giving a broad overview of relevant activities in the biological area and with a view to proposing how a future new EU proliferation prevention programme could be structured and what it might include.

No attempt has been made to evaluate the efficiency or need for reform of the International Science and Technology Centre (ISTC) or the Science and Technology Centre in Ukraine (STCU) projects in the life sciences.[15] Visits have been made to US

[12] Gannon, John C. (Chairman, National Intelligence Council), 'The global infectious disease threat and its implications for the United States', NIE 99-17D, Jan. 2000; and Leitenberg, M., 'Assessing the biological weapons and bioterrorism threat', Presented at Meeting the Challenges of Bioterrorism: Assessing the Threat and Designing Biodefence Ctrategies, Furingen, Switzerland, 22–23 Apr. 2005.

[13] United Nations Secretary-General's foreword in 'A more secure world: Our shared responsibility, Report of the Secretary-General's High-level Panel on Threats, Challenges and Change', 2004.

[14] Koblentz, G., 'Pathogens as weapons; The international security implications of biological warfare', *International Security*, vol. 28, no. 3 (winter 2003/2004), pp. 84–122.

[15] Background paper 8 for this conference focuses on the science centres.

government departments (State, Defense and Energy) as well as non-governmental bodies—the Monterey Institute of International Studies, the Center for Nonproliferation Studies, the Center for Strategy and International Studies, the Russian American Nuclear Advisory Council and the Nuclear Threat Initiative (NTI)—including contacts with the Civilian Research and Development Foundation. Contacts were also made with the ISTC, the STCU, Canada, Finland, the United Kingdom (UK), France and the European Commission Directorate General (DG) for Research, including a visit to Luxembourg to the European Commission Directorate Public Health and Risk Assessment, Health and Consumer Protection DG. Because of time constraints, other meetings with different parts of the European Commission or Council entities or with the new European Centre for Disease Prevention and Control (ECDC) were not possible to fit in. Information has not yet been received from France on its activities.

One major limitation has been that no official visit to discuss the biological area in Russia could be arranged. This also meant that it has been possible to collect only very limited information on the official Russian view on threat reduction activities in the biological area. To compensate for this some limited contacts were made with representatives from institutes in Russia as well as the newly independent states (NIS).[16] It should be noted that the US government departments have been very helpful with information on projects, as have other government representatives or non-governmental bodies visited.

Biological threat reduction, bio-safety and bio-security activities in the EU

The European Security Strategy adopted by the European Council in December 2003 identifies the proliferation of WMD as a key and potentially the greatest threat for EU security.[17] This is further elaborated in the WMD Strategy. To meet this challenge the EU must act with resolve, using all the instruments and policies at its disposal. The objective is to prevent, deter, halt and, where possible, eliminate proliferation programmes of concern worldwide.[18]

The EU WMD Strategy states that:

> although effective deployment of biological weapons requires specialized scientific knowledge including the acquisition of agents for effective dissemination, the potential for the misuse of the dual-use technology and knowledge is increasing as a result of rapid developments in the life sciences. Biological weapons are particularly difficult to defend against (due to their lack of signature). Moreover, the consequence of the use maybe difficult to contain depending on the agent used and whether humans, animals, or plants are the targets. They may have particular attractions for terrorists. Biological weapons, as well as chemical weapons, pose a special threat in this respect.

In existing EU documents a number of interrelated issues can already be found that are relevant for a programme on biological threat reduction and enhancing bio-security.

- In 2002 the EU committed €1 billion over 10 years to the G8 Global Partnership.

[16] The newly independent states are Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.

[17] European Union, 'European Security Strategy: A secure Europe in a better world', Brussels, 12 Dec. 2003, <http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/reports/78367.pdf>.

[18] Council of the European Union, 'EU strategy against proliferation of weapons of mass destruction', Doc. 15708/03, Brussels, 10 Dec, 2003, <http://ue.eu.int/uedocs/cmsUpload/78367.pdf>; and Council of the European Union (note 1).

- The need to increase EU cooperative threat reduction funding (including setting up programmes of assistance and measures aimed at reinforcing the control of the non-proliferation of WMD-related expertise, science and technology) is recognized. More specifically, examination of information provided by Member States on their bilateral assistance programmes led to the conclusion that there is scope for EU initiatives in the field of BW. There is an identified need to study and evaluate the setting up of an institute aimed at employing scientists from regions other than the FSU (starting by looking at Libya, Iraq and Iran) to promote the use of critical expertise and skills in peaceful applications.
- Reinforcing the BTWC in this context, continuing reflection on verification instruments.
- Setting up a programme of assistance to states in need of technical knowledge in order to ensure the security and control of sensitive material, facilities and expertise.
- Fostering measures aimed at ensuring that any possible misuse of civilian programmes for military purposes will be effectively excluded.
- Reinforcing the efficiency of export controls.
- Reinforcing cooperation between non-proliferation, public health, occupational health and safety structures.
- Strengthening of European Community (EC) and national legislation and control over pathogenic micro-organisms and toxins (both in Member States and in acceding countries) where necessary.
- The issue of promoting bio-security and bio-safety standards in and outside the EU.
- Fostering dialogue with industry to reinforce bio-security awareness. An initiative will be taken in order to promote (a) a dialogue with industry in the EU countries with a view to raising the level of awareness of problems related to WMD, and (b) a dialogue between industry in the EU countries and the USA, in particular in the biological sector.
- In the context of EU's Strategic Partnership with the Mediterranean and the Middle East, consideration should be given to cooperation and assistance programmes tailored to each specific situation. In the context of implementation of the EU WMD Strategy Iran, Iraq and Gulf Cooperation Council (GCC) states could be of major interest, including promoting a vision of a WMD-free zone.

Most public health issues are identified as the competences of the EU Member States. The Health Security Committee and relevant working groups focus to keep a balance between the requirements to ensure 'domestic controls' by bio-security measures and the general requirements for public health, such as diagnostic needs, surveillance, epidemiological activities, outbreak controls and response.[19] The way in which the EU uses the expressions 'bio-safety' and 'bio-security' may need to be examined given that legislation is regularly adapted to technical progress, changes in international regulations or specifications and new findings. In 2002 a Community Action in the field of public health was adopted covering the years 2003–2008. Priority areas are health information, threats and determinants, including cooperation with the WHO on health monitoring and disease surveillance. The programme also covers health security, policy

[19] Council of the European Union (note 1).

and procedures, and preparedness.[20] There are clinical guidelines for bio-terror agents[21] and a list of agents has been elaborated.[22] Community legislation on health and safety, including bio-safety at work, aims to reduce the risks related to the storage and manipulation of pathogenic agents to levels that are not significant from the health point of view. It also relates to the protection of agents, with measures such as adequate containment levels and rules for conduct, in general and or personal protection measures, notification procedures and health surveillance measures. There are specific provisions for the qualifications, training and experience required to increase the safety of manipulating pathogenic agents. Concerning bio-safety, there are European Community directives in the area of occupational health and safety.[23] They also require appropriate qualifications and registering of those involved in all of the above operations, an aspect which relates to bio-security aspects. Strict conditions and safeguards also apply in the food safety and veterinary and plant health sectors.[24]

Concerning other aspects of bio-security, the responsibility for measures lies with the Member States.[25] Surveillance is vital for rapid containment, response and control of outbreaks of human, animal and plant diseases that have the potential to adversely impact on public health and/or disrupt trade, travel and even food security. In establishing national legislation in these areas there are guidelines for the transport of dangerous materials, with the latest update from the WHO in 2004.[26]

European legislation exists to deal with genetically modified organisms,[27] including, in areas of major importance to health security, measures and actions in the areas of

[20] Decision No. 1786/2002/EC of the European Parliament and of the Council of 23 September 2002, adopting a programme of Community action in the field of public health (2003–2008), *Official Journal of the European Communities*, L 271, 10 Sep. 2002.

[21] European Commission, 'European clinical guidelines for bioterror agents', <http://europe.eu.int/comm/health/ph_threats/Bioterrorisme/clin_guidelines_en.htm>.

[22] European Agency for the Evaluation of Medicinal Products, 'EMEA/CPMP guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism', Doc. CPMP/4048/01, London, 25 July 2005.

[23] There are European Community directives in the area of occupational health and safety, notably directives 89/391/EC on improvements of health and safety at work, 89/656/EC on personal protective equipment, and 98/24/EC on the protection of workers from risks related to chemical agents. Bio-safety measures to protect the environment and the workplace are also regulated by EU legislation. Directive 2000/54/EC of the European Parliament and of the Council of 18 Sep. 2000 on the protection of workers from risks related to exposure to biological agents at work (7th individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), *Official Journal of the European Communities*, L 262 (17 Dec. 2000), pp. 0021–0045.

[24] European Standards EN 12128, 12738, 12740 and 12741 define, respectively, containment levels, guidance for containment, handling of wastes, and guidance for the operation of laboratories.

[25] Council of the European Union, 'Draft European Union report on the implementation of the UNSC Resolution 1540', Doc. 13985/04, Brussels, 27 Oct. 2004.

[26] WHO, Department of Communicable Disease Surveillance and Response, 'Transport of infectious substances; Background to the amendments adopted in the 13th revision of the UN Model Regulations guiding the transport of infectious substances', Doc. WHO/CDS/CSR/LYO/2004.9, 2004; United Nations, Recommendations on the Transport of Dangerous Goods – Model Regulations, 13th revised edn, 2003, <http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html>; United Nations Recommendations for the Transport of Dangerous Goods, ST/SG/AC, 10/Rev9, 1995; Guidelines for the safe transport of infectious substances and diagnostic specimens, Geneva, WHO/ECM/97.3, 1997; and International Civil Aviation Organization (ICAO), Technical instructions for the safe transport of dangerous goods by air, ICAO-TI, 1995/96 Ed and IATA-DGR, 1994.

[27] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms, *Official Journal of the European Communities*, L117, 8 May 1990; Directive as last amended by Directive 98/81/EC, *Official Journal of the European Communities*, L330, 5 Dec. 1998; Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release of genetically modified organisms into the environment has been applicable since 17 Oct. 2002, *Official Journal of the European Communities,* L 106, 17 Apr. 2001; and Directive as amended by Council Decision 2002/811/EC, *Official Journal of the European Communities*, L280, 18 Oct. 2002. The European Parliament and the Council adopted, on 15 July 2003, a Regulation on trans-boundary movements of genetically modified organisms. Under Article 14, Member States shall take appropriate measures to prevent unintentional trans-boundary movements of GMOs. As soon as they are aware of such a movement that is likely to have significant adverse effects, they must inform the public and the Commission and

food, animal, plant and water safety.[28] In the animal health area, there is a complete set of Community legislation in place to prevent and control animal disease outbreaks, including provisions on Member States' contingency plans against major animal diseases.[29] In 1993 the European Community agreed to the UN Convention on Biological Diversity.[30] The EC and 14 of the (then 15) Member States signed the Biosafety Protocol on 24 May 2000.[31]

From this brief overview it can be noted that EU has no agreed view on the scope of application of the term bio-security and no clear legislative approach in this area. However, a number of issues and matters of relevance are scattered across different parts of the EU. Greater clarity is badly needed.

consult the affected or potentially affected states to enable them to determine appropriate responses. *Official Journal of the European Union*, L 287, 5 Nov. 2003.

[28] Gouvras, G., 'Policies in place throughout the world: Action by the European Union', *International Journal of Infectious Diseases, Smallpox Biosecurity: Threat Policy Science*, vol. 8, supplement 2, 852 (2004), pp. 521–30.

[29] European Council, Directive 2003/89/EC on Community measures for the control of foot-and-mouth disease, 29 September 2003; European Council, Regulation (EC) No 21/2004 establishing a system for the identification and registration of ovine and caprine animals that will improve the tracing of animals, including those that have been subject to CB-attacks, 17 December 2003.

[30] Decision 93/626/EEC, *Official Journal of the European Communities*, L 309, 13 Dec. 1993.

[31] Council Decision of 25 June 2002 (2002/628/EC) concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety, *Official Journal of the European Communities*, L201/48, 31 July 2002. Luxembourg signed the convention on 11 July 2000.

2. Background

During World War II a number of states initiated BW programmes, but after the war only the USA and the Soviet Union put major resources into further developing large-scale military capabilities. These programmes, together with other WMD programmes, were at the centre of the cold war arms race. To promote the adoption of the negotiated BTWC, the USA unilaterally destroyed its BW stockpile in 1969. There was no similar action from the Soviet Union, and from that time mistrust has remained in this area between the two states. It was later found out that the Soviet Union did not believe the USA was abandoning BW, and to counter this it greatly increased activity in the area of developing improved BW, using recent scientific breakthroughs in biotechnology.[32]

The legacy of the BW programme of the former Soviet Union

The Soviet Union built up the world's largest BW programme. The pursuit of BW was systematic and, from the start, large-scale in terms of money, facilities and personnel. Moreover, the programme always had the political support of the highest Soviet leadership but has rarely been officially acknowledged. A new phase came in the 1970s when a new, secret organization for research and production called Biopreparat was created that would focus on fundamental problems in molecular biology and genetics, and the development of advanced technology for the military.[33]

The size of the former Soviet BW programme and the number of facilities involved are still not clear because of the lack of openness and transparency on the part of the Russian authorities. Figures cited are a total of 20–50 facilities and *c*. 65 000 personnel within its BW complex, including 40 000 in Biopreparat, 15 000 in the Ministry of Defence and an additional 10 000 in Ministry of Agriculture facilities.[34] US experts have estimated that 9000 of those people have substantial BW expertise but it is unclear how many remain in the former Soviet states and how many can have left for research jobs in the USA, Europe or other countries. About 50 different human and animal pathogens, from plague, anthrax, brucella and tularaemia bacteria to smallpox, Marburg and Ebola viruses were being studied. Some strains were genetically altered to increase potency or resist antibiotics and vaccines.

The Soviet BW programme reached the stage where weapons were produced. The Ministry of Defence directed the BW programme with several of its own facilities, for example, the Institute of Microbiology in Kirov, Sverdlovsk (now Yekaterinburg), Zagorsk (now Sergiyev Posad), the Institute of Military Medicine in Leningrad (now St Petersburg), a facility at Strizhi and a test ground on Vozrozhdeniye Island. The Strizhi facility has been said to be in the process of being demilitarized for several years and was then supposed to be open for foreign investment. Biopreparat had mobilization facilities on Russian territory at Berdsk, Kurgan, Omutninsk and Penza, and on Kazakh territory at Stepnogorsk. In addition, however, mobilization capacity was also retained at the Ministry of Agriculture's Pokrov Factory of Biopreparations in Vladimir oblast.

[32] Rimmington, A., 'Invisible weapons of mass destruction: The Soviet Union's BW programme and its implications for contemporary arms control', *Journal of Slavic Military Studies*, vol. 13, no. 3 (Sep. 2000), pp. 1-46.

[33] Rimmington (note 32).

[34] Alibek (note 7); Adams, James, 'The weapons of special designation', chapter in *The New Spies: Exploring the Frontiers of Espionage* (Hutchinson: London, 1994), pp. 270–83; and Smithson, A. E., *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes*, Report No. 32 (Henry L. Stimson Center, Dec. 1999), p. 9.

These production plants incorporated capacity for the wartime production of hundreds of tonnes of a range of biological agents.[35] In Stepnogorsk 500 metric tonnes of anthrax bacteria could be produced in 300 days. In 1992, President Boris Yeltsin acknowledged in a decree On Ensuring the Implementation of International Pledges in the Sphere of Biological Weapons[36] that there had been a breach of the BTWC and that further offensive BW work would be banned. It was also stated that the number of personnel working in this area would be decreased by half and the funding by 30 per cent.[37] This was formulated in the joint statement issued by UK, the USA and Russia in 1992.[38]

In addition, a number of research and development (R&D) institutes existed in the biological area, some of which were responsible for epidemiological surveillance and studies of dangerous infectious diseases—such as the system of six anti-plague institutes with numerous epidemiological stations. Some institutes were central reference institutes like Gamalya. The civilian facilities of the former Soviet BW programme, under Biopreparat, have been opened up to foreign support programmes step by step, but in spite of this there is still a marked lack of knowledge about and transparency of the historical, present and future activities at these facilities. Foreign conversion has mainly been directed to redirecting scientists, and has only been initiated on transforming some of the huge production facilities.

There is a potential environmental problem due to the legacy of the former BW programme. It is not known how many former production or other facilities that no longer are in operation there might be, or how many previous BW test sites might exist in Russia. The anthrax decontamination work conducted on Vozrozhdeniye Island by the USA was assessed as successful but follow-up environmental monitoring will be necessary for the foreseeable future, and the presence of other pathogens or chemical agents cannot be disregarded. Other test sites are not currently known. The fact that Vozrozhdeniye Island ceased to be an island in 1996 has made the problem even more complicated as rodents or other animals could now spread diseases to the mainland. Another serious problem is the animal burial sites on the island, which was used as a BW testing ground up to 1992. Disease agents causing tularemia, plague, cholera, brucellosis, typhus, Q fever, botulinum toxin and Venezuelan equine encephalitis are known to have been field-tested and used for experiments on the island. A similar general problem is the burial sites of cattle that died from the 1979 anthrax release in Sverdlovsk, which might cause health hazards in the event of high flooding.[39] This could well also be a problem in other areas, and in most cases the burial sites are not known.

The break-up of the Soviet Union brought about vaccines shortages and a decline in vaccine quality in Russia. Improvements are now being made thanks to foreign investment. The Russian vaccine industry has a huge capacity for the production of bacteria and viruses, the major part of which appears to be in the facilities for veterinary vaccines. The standards of the facilities and equipment vary and improvements have

[35] Rimmington (note 32), pp. 1–46.

[36] Decree of the President of the Russian Federation, Edict no. 390, 11 Apr. 1992.

[37] Leitenberg, M., 'The possibilies and limitations of biological weapons conversion', in E. Geissler, L. Gazso and E. Buder (eds), *Conversion of Former BTW Facilities*, NATO Science Series, 1 Disarmament, pp. 119–33.

[38] Roffey, R, Unge, W., Clevström, J. and Westerdahl, K., 'Support to threat reduction of the Russian biological weapons legacy: Conversion. Biodefence and the role of Biopreparat', Swedish Defence Research Agency (FOI) Report, 2003.

[39] 'Russian officials warn spring floods could spread anthrax in Urals', BBC Monitoring International Reports, 15 Apr. 2005.

been initiated both at individual facilities and for the industry as a whole.[40] It is also well known that the situation concerning infectious diseases in Russia and the NIS countries is a serious problem in many aspects. Anecdotal reports persist of former Soviet scientists, especially those from Central Asia and the Caucasus, being approached by officials from proliferant states. Further, a 2003 survey of Russian scientists with weapons expertise found that 20 per cent of respondents would consider working in North Korea, Syria, Iran, or Iraq for a year or more.[41]

The former Iraqi and other BW programmes

Iraq acquired a BW capability and the first field tests with BW were done in 1987. In 1995 Iraq declared that it had filled 25 Al-Hussein warheads with BW (botulinum toxin, aflatoxin and anthrax bacterial spores), and 157 R400 aerial bombs were produced for BW but it is unclear exactly how many were filled or with which of the three agents. Iraq had also declared that there were projects to develop aircraft drop-tanks to disseminate BW. According to the Iraq Survey Group (ISG) which investigated Iraq's WMD activities on behalf of the USA and allies after the latest war, the assessment was that Iraq maintained its objective of keeping a latent BW capability after 1991 by saving what it could of its BW infrastructure and covertly continuing BW research. Iraq also hid any evidence of the previous programme and destroyed existing stocks. The ISG judged that the BW programme was in reality abandoned in 1995 as it would constitute a potential embarrassment and its discovery would hinder any relief on UN sanctions. However, there are still uncertainties concerning the exact numbers of filled weapons, as well as bulk amounts of agent. No evidence has been found of mobile BW production vehicles.[42] While a number of enquiries have been carried out to investigate why intelligence agencies exaggerated the WMD threat before the war,[43] the UN inspectors appear to have had a generally accurate assessment of Iraq's illicit programmes despite limited resources, even if deception methods were used to mislead outsiders—something that is in line with the way offensive programmes have been operated in other countries. It is not known how many Iraqi scientists with essential know-how have been able to leave the country.[44]

Apart from Iraq, based on intelligence information mainly from the USA, it has been assessed that around 10 states might be trying to acquire a BW capability. Iraq, North Korea, Iran, Syria and Cuba have all been named.[45] These claims have been made for a

[40] Westerdahl, K. S. and Roffey, R., 'Vaccine production in Russia: An update', *Nature Medicine* Vaccine Supplement, vol. 4, no. 5 (May 1998).

[41] US Department of State, *Annual Report to Congress*, Dec. 2004.

[42] Duelfer, C., 'ISG Iraq report', Key findings, Oct. 2004.

[43] Butler, L., Review of intelligence on Weapons of Mass Destruction, Report of a Committee of Privy Counselors, Ordered by the House of Commons, The Stationery Office, London, HC 898, 14 July 2004; 'Hutton Report: The aftermath: Dr Jones' warning memo may well turn out to have been a far-sighted move', *The Independent*, 4 Feb. 2004; Intelligence and Security Committee, Report on Iraqi Weapons of Mass Destruction: Intelligence and Assessments, <http://wwwcabinet-office.gov.uk/reports/isc>; and Report on the US intelligence communities' prewar intelligence assessments on Iraq, Chapter IV Intelligence Community analysis of Iraq's biological weapons programme, pp. 143–94, Select Committee on Intelligence United States Senate, 108th Congress, 7 July 2004.

[44] 'Derelict plant, angry scientists highlight gap—so far—between US weapons charges and Iraq reality', Associated Press, 4 Oct. 2003.

[45] US Department of State, Office of International Programmes, 'CIA report documents weapons proliferation trends', *Washington File*, 8 Jan. 2003, <http://www.usinfo.state.gov>; Bolton J. R., 'The Bush Administration's nonproliferation policy: Successes and future challenges: Testimony by Under Secretary of State for Arms Control and International Security', House of International Relations Committee, 30 Mar. 2004; Graham, T. W., 'Weapons of mass destruction: Does globalization mean proliferation?', *Brookings Review*, vol. 19, no. 4 (2001), pp. 38–39; Sqassoni, S., 'Globalizing Cooperative Threat Reduction: A survey of options', CRS Report for Congress, Library of Congress, Congressional Research Service, RL 32359, 15 Apr. 2004; Roffey, R. *et al.*, *Iran's Disarmament and Arms*

number of years but few supporting facts have been presented. Recent assessments by the United States have taken a more cautious approach to describing alleged programmes and capabilities in countries such as Cuba, Iran and Syria.[46]

The enhanced risk of bio-terrorism

The terrorist attacks in the USA on 11 September 2001 and further terrorist incidents since then underlined a major threat to international peace and security. According to Europol the threat of terrorist actions within the EU is posed by a wide number of groups and organizations, ranging from international Islamic extremist networks and large-scale nationalist groups down to violent political extremist activists, generally carrying out acts of sabotage and criminal damage.[47]

The risk of bio-terrorism is not and cannot be disregarded by the EU, even if it is very difficult to point to exactly which groups could use this kind of means and which would be the most probable targets of the EU Member States, or within each state. Although the degree of threat can be assessed as rather different from that in the USA (and many Europeans believe that the USA overreacted to the anthrax letters), there have been several recent cases of law enforcement authorities in several Member States stopping what they believed were plans to use biological or chemical agents in attacks.[48]

Outbreaks of infectious diseases and collections of dangerous pathogens and toxins worldwide

The emerging and re-emerging infectious diseases are a worldwide problem and a global strategy is needed to handle them. One example of the risks involved was seen recently when a laboratory by mistake sent out proficiency tests that included pandemic flu virus to 3750 laboratories round the world, and then urgently had to ask all laboratories to destroy their samples. It has also been difficult to track down all samples as some seem to have gone missing. The error was first detected one month after the samples had been sent, as a result of a mistaken patient diagnosis due to contamination from the proficiency test kit sample.[49] In the EU estimates of the number of casualties that a pandemic influenza epidemic could cause amount to 2–3 million deaths.

Control Policies for Biological and Chemical Weapons, and Biological Capabilities, FOI report 0981-SE, 2003; 'Cuba denies US claims of links with bio-terrorism', Xinhua General News Service, 7 Oct. 2003; 'Syria has no chemical or bacteriological weapons: Assad', TASS, 12 May 2003; 'Assad says Israel must give up nuclear weapons first', Agence France-Presse, 21 Jan. 2004; 'North Korea reportedly admits to biological, chemical weapons', BBC Worldwide Monitoring, 5 Nov. 2002; Leitenberg, M., 'Biological weapons in the twentieth century: A review and analysis', *Critical Review in Microbiology*, vol. 27, no. 4 (2001), pp. 267–320; '4 nations thought to possess smallpox: Iraq and North Korea named, two officials say', *Washington Post*, 5 Nov. 2002, p. A01; 'United States extends the evil axis', *Defense and Security*, 13 May 2002; and 'Chemical and ABO weapons in Darfur likely to have been of Syrian origin', *Defense and Foreign Affairs Daily*, 21 Sep. 2004.

[46] US Central Intelligence Agency (CIA), 'Unclassified Report to Congress on the acquisition of technology relating to weapons of mass destruction and advanced conventional munitions, Attachment A, 1 July through 31 December 2003', <http://www.cia.gov/cia/reports/721_reports/july_dec2003.htm#chemical>.

[47] Non-confidential report on the terrorist activity in the European Union from October 2002 to October 2003, Terrorist activity in the European Union: Situation and trends report (TE-SAT), October 2002–15 October 2003, The Hague, 03 December 2003, File number 2566-324, Doc. 15877/1/03 ENFOPOL 120 REV 1.

[48] Interview with Pierre Bosquet de Florian (Head of the Direction de surveillance du territoire (DST), France), *L'Express*, 27 Nov. 2003; 'Group warns Europe of more terror attacks', Associated Press, 2 July 2004; 'British court charges 4 men as terrorists, arrests spread', *New York Times*, 14 Jan. 2002, section A, p. 13; 'Terrorist chemical threat "worse than suspected"', *Financial Times*, 11 Apr. 2004; Eric Coddy, Matthew Osborne, and Kimberly McCloud, 'Chemical Terrorist Plot in Rome?', Research Story of the Week, Center for Nonproliferation Studies, Monterey Institute of International Studies, accessed at <http://cns.miis.edu/pubs/week/020311.htm>, 19 Mar. 2003.

[49] 'Labs race to destroy flu virus after test kit mistake', *Financial Times* (London), 14 Apr. 2005; and 'Virus scare shows need for better disease-control methods', *Vancouver Sun*, 15 Apr. 2005.

The rapid social and economic change now taking place, combined with increased travel, is affecting this in ways that are difficult to forecast. The infectious disease situation, the discrepancies in epidemiological disease surveillance systems, and weaknesses in diagnostic capabilities, preparedness and response capacities in countries in the EU's neighbourhood are of immediate concern for EU Member States. This is also the case with bio-security, which is a question some Western (although few EU) countries have only recently begun to focus on more seriously. Looking further there are large numbers of laboratories in the world which have and/or work with dangerous pathogens or toxins, but there is no information on their numbers as no inventory has been made. Very few countries have such inventories today. It is known that around 1500 state-owned and commercial culture collections exist worldwide,[50] not taking into account all the culture collections of various types at universities, hospitals, laboratories or commercial companies that do not trade in agents. An example is an inventory of laboratories with the polio virus where it was found that there were 260 000 laboratories not including laboratories in China. There is a need to initiate studies to see how big the problem is and to study the level of bio-safety and bio-security worldwide.

Nor is there is information on how large the traffic of transfers of dangerous pathogens on a global scale is or how much is transferred bypassing current regulations. One way used to send samples was to indicate that it was a medical sample of no value and not indicate whether there were any micro-organisms in it. There are also very few examples of theft or illicit transfer of dangerous pathogens from the FSU states so far as is known from open sources of information. It has been reported in one case that a man tried to enter the laboratory of the Kazakh Scientific Centre of Quarantine and Zoonosis Infections. His attempt was thwarted thanks to good security.[51] This does not mean that the problem does not exist, as it would be extremely difficult to detect a theft of agent by an insider in a facility. Nor is there any means except intelligence to detect transfers across borders as only very small quantities would be required and are easily hidden.

[50] Tucker, J., 'Preventing the misuse of pathogens: The need for global standards', *Arms Control Today*, June 2003, <http://armscontrol.org/act/2003_06/tucker_june03.asp>.

[51] 'Kazakhstan: Man arrested in bio weapons center', *Almaty Herald*, 11 Nov. 2002; and 'Kazakhstan experts discuss ways of preventing bioterrorism', from *Kazakhstanskaya Pravda* (Almaty, in Russian), 22 Sep. 2004, p. 6, BBC Monitoring International Reports, 24 Sep. 2004.

3. The main security-building approaches

Risk assessment for facilities

Biological agents including dangerous pathogens are widely distributed globally and held in thousands of laboratories, clinical facilities or commercial companies. In many cases they can be isolated from nature. Since micro-organisms are also self-replicating, extremely small quantities are required to permit mass production given the right growth conditions. The biological agents and toxins can be in a number of places in a facility if they are used or being studied in addition to pure cultures; they are stored in the same freezers and so on. The approaches for handling biological material are often somewhat different for human, animal and plant pathogens and for toxins. There is a need to develop standards and procedures for how these especially dangerous pathogens should be stored, transferred, handled or disposed of in a safe and secure way.

Risk assessment methods can be a great help to identify the risks and grade them. In general it can be said that the main risk probably comes from insiders rather than outsiders. Insiders will know the facility and its working routines, have access, and also be knowledgeable about the pathogens and how to handle them safely. Categories of outsider that can be difficult to protect against include visiting scientists, students, and short-term maintenance workers. These are not the traditional threat group that high-security systems have been designed to protect against. A careful evaluation is needed of the assets that need protection in a facility in order to identify potential threats, to perform security risk assessments and determine the required bio-security system in each case. This information is necessary if the performance objectives of the bio-security system are to be designed and set. However, a balance between security and research must be achieved in order to protect critical assets as well as allow vital bio-science to advance.

The bio-security system could then be designed to have graded levels depending on the type of assets to be protected. Dangerous pathogens and toxins can be placed in different bio-security levels. The risk classification would then have to take into account the probability that an agent would be used by terrorists (depending on factors such as the availability of suitable strain, ease of production, mode of dissemination, the hardiness of the agent and required know-how) and the consequences of use (depending on agent, infectious dose, pathogenicity, modes and ease of transmission, availability of countermeasures and so on).[52] The category of risk an agent represents when evaluated from this perspective will not necessary correspond to its bio-safety risk level. Most biological agents would be evaluated as minimal security risk. The highest level of security would be required for only a very few agents, including material the loss of which would have national or international security consequences and that have been eradicated from nature.[53] This would include highly dangerous pathogens such as small-

[52] Kwik, Gigi *et al*., 'Biosecurity: Responsible stewardship of bioscience in an age of catastrophic terrorism', *Biosecurity and Bioterrorism: Biodefense Strategy, Science, and Practice*, 1:1 (2003), pp. 27–36; and Steinbruner, John *et al*., 'Controlling dangerous pathogens: A prototype protective oversight system', CISSM Working Paper, 5 Feb. 2003, <http://www.puaf.umd.edu/CISSM/Publications/AMCS/finalmonograph.pdf>.

[53] Gaudioso, J. and Salemo, R. M., 'A conceptual framework for biosecurity levels', Paper presented at BTR 2004: Unified Science and Technology for Reducing Biological Threats and Countering Terrorism, University of New Mexico, Albuquerque, 18–19 Mar. 2004, SAND 2004-0759C, 2004; and Salerno, R. M. *et al*., 'Balancing security and research at biomedical and bioscience laboratories', *BTR 2003: Unified Science and Technology for Reducing Biological Threats and Countering Terrorism—Proceedings* (Albuquerque, NM: Mar. 2003).

pox and genetically modified agents requiring the strictest security measures,[54] which are only needed for very few laboratories. The next level would include pathogens and toxins that are difficult to use as weapons and will only cause local consequences, and the last level would be pathogens and toxins with a low probability of use. A bio-security level system could consist of:[55] physical protection, personnel reliability, adequate scientific and commercial oversight, pathogen accountability, transport security and information security.

Enhancing physical security

The obvious need is to install video cameras for monitoring purposes and establish a fence or other physical barrier surrounding a facility to prevent unauthorized access. In many areas of the world there are major deficiencies when it comes to the physical security, but many aspects of what has been done to improve bio-safety will also enhance physical security. Similar approaches to bio-safety are being taken by states nationally, regionally and more widely to address safety in the storage, handling and use of pathogenic micro-organisms and toxins. The aim of physical security measures is to limit access to a facility or parts of a facility to authorized personnel, detect unauthorized access, and respond to incidents. Other measures such as perimeter security, access to culture collections and a log and register of users are likely to be required for bio-safety reasons but will also contribute to the security of pathogenic micro-organisms and toxins. However, the requirements for facilities working with toxins will generally be less stringent. The bio-safety equipment and the professional bio-safety officer that many facilities have are primarily required for bio-safety reasons but will also have a function and a role to enhance bio-security. In constructing new facilities bio-security as well as bio-safety aspect should be taken into account at the design stage.

Management, personnel and handling

For the management it is important to promote a security culture in the facility based on common values among the personnel and that they believe the security measures taken or proposed really matter. The security practice has to be part of good managerial practice.[56] The management's attitudes and behaviour, from the national to the local level, will be critical to how bio-security issues are viewed in organizations and facilities. There is already a security, safety and quality culture in all organizations, even if it is not articulated. Careful selection of personnel that are to work with dangerous pathogens and toxins is very important. A background check from a security point of view should be part of a recruitment procedure for this type of specialist work. Controlling by recording those working in the facility also contributes to ensuring the security of materials and provide a basis on which to add further or more stringent bio-security requirements if needed. One essential part is information security for handling sensitive bio-security-related information. Security is important with regard to access to

[54] Salemo, R. M. and Estes, D. P., 'Biosecurity: Protecting high consequence pathogens and toxins against theft and diversion', Sandia National Laboratories, Albuquerque, SAND No. 2003-4274P, Oct. 2003.

[55] Salerno, R. M., Barnett, N. and Koelm, J., 'Balancing security and research at biomedical and bioscience laboratories', *BTR 2003: Unified Science and Technology for Reducing Biological Threats and Countering Terrorism—Proceedings* (Albuquerque, NM, Mar. 2003); and Health Canada, Population and Public Health Branch, Office of Laboratory Security, Material and Safety Data Sheet, Jan. 2000, <http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/msds40e.html>.

[56] Khripunov, I., Nikonov, D. and Katsva, M., 'Nuclear security culture: The case for Russia', in I. Khripunov and J. Holmes (eds), Center for International Trade and Security, University of Georgia, Dec. 2004.

and handling of dangerous pathogens. The requirements for storage, containment, custody and disposal of pathogenic micro-organisms should be reviewed to see whether these need to be made more stringent to satisfy bio-security requirements.

Accountability, licensing and accreditation

A system for accountability with procedures for tracking the storage, use or transfers of dangerous pathogens could be required. Controls/registration/licensing of facilities and individuals involved in work on or the handling of dangerous pathogens or toxins should be seriously considered. It is evident that in a few states there are procedures for the licensing and accreditation of individuals working with pathogenic micro-organisms and toxins of concern. Such licensing is frequently for a limited duration of perhaps two or five years with provisions for the individuals to be inspected or screened to determine whether they meet the national legislation and regulation requirements.[57]

Transfer between facilities, and in-country and trans-boundary of infectious substances and toxins

Many states have introduced controls for the import and/or export as well as transfers within a country of dangerous human, animal or plant pathogens. In some cases dangerous pathogens or toxins can only be transferred between approved or licensed facilities to further reduce risks. In some cases the listed organisms are the same for national transfers as for export controls. There are internationally agreed standards for the transportation of dangerous pathogens and for toxins (which are generally treated as chemicals), including the requirements for the containers and/or packaging to be used for such transportation.[58] Many governments have transposed the provisions of the UN Model Regulations into their own legislation for domestic traffic. There is a worldwide harmonization with respect to packaging and shipping requirements.[59] The key changes made are the move from risk group classification of pathogens to that of categories of infectious substances (transport categories A and B) based on scientific assessment of risk to humans and animals, as well as a clarification of instructions for packaging infectious substances and clinical specimens. The various types of dangerous goods involve taking special measures so that the potential risks are adequately communicated to all who may come in contact with the goods through special markings and labels indicating the hazards of a consignment and inclusion of relevant documentation.

[57] Tucker (note 50).

[58] International Air Transport Association (IATA), Dangerous Goods Regulations, <http://www.iata.org/dangerousgoods/index>; IATA, 'Infectious substances shipping guidelines', Montreal, 2003, <http://www.iata.org/ads/issg.htm>; International Civil Aviation Organization (ICAO), 'Technical instructions for the safe transport of dangerous goods by air', 2003–2004 edn, Montreal, 2002; Universal Postal Union (UPU), Universal Postal Convention, <http://www.upu.int/index.html>; United Nations Economic Commission for Europe, Inland Transport Committee, 'Restructured ADR applicable as from 1 January 2003', United Nations, 2002, <http://www.unece.org/trans/danger/publi/adr/adr2003/ContentsE.html>; International Maritime Organization (IMO), International Maritime Dangerous Goods (IMDG) Code, <http://www.imo.org/Safety/index.asp?topic_id=58>; United Nations, 'Work of the Committee of Experts on the Transport of Dangerous Goods: Report by the Secretary-General', UN document E/1999/43, 19 Apr. 1999, <http://www.un.org/documents /ecosoc/docs/1999/e1999-43.htm>; and United Nations, 'Work of the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals: Report by the Secretary-General', UN document E/2001/44, 17 Apr. 2001, <http://www.un.org/documents/ecosoc/docs/2001/e2001-44.pdf>.

[59] International Regulations for the Safe Transport of Biological Materials Prepared by the Federal Republic of Germany, BWC/MSP.2003/MX/WP.59.

The Model Regulation defines suitable packaging affording a level of safety appropriate to the degree of risk.[60] The new transport categories are defined as: (a) Category A—an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Listed in category A are 49 human pathogens and 14 animal pathogens; and Category B—an infectious substance which does not meet the criteria for inclusion in category A.

Developing standards, codes of practice and legislation

Most states have regulations and standards for the level of bio-containment of pathogenic micro-organisms in order to ensure that the risk of accidental release is reduced to a level appropriate to the hazard posed by the pathogenic micro-organisms. The bio-containment standards generally have four levels. Facilities engaged in handling toxins, and not the micro-organisms producing the toxins, will generally be regarded as chemical facilities with standards appropriate to the hazards posed by the toxin. The bio-containment requirements also include provisions, particularly for those pathogens presenting particular hazards, to restrict access to nominated persons and to require safe storage, and for the highest bio-containment level, secure storage, which form a basis for providing security provisions to prevent unauthorized access to or unauthorized acquisition of pathogenic micro-organisms and toxins.

It should be noted that other standards apply to facilities carrying out genetic manipulation. These also generally have four levels corresponding to the risk posed by the genetic modification. While these containment levels are again established for bio-safety reasons rather than for security reasons, they include provisions, particularly for those genetic modification activities which present the highest risk, to restrict access to authorized personnel only and to require safe and secure storage.

Codes of practice that complement legislation and regulations may be produced by national authorities to set out how these should be implemented. There are a number of these common practices, such as the Good Manufacturing Practice (GMP),[61] Good Laboratory Practice (GLP)[62] and Good Microbiological Technique (GMT),[63] which should be promoted. There is a need to intensify training and education concerning bio-safety and bio-security as well as promote other codes of practice and codes of conduct for scientists in Russia and the NIS. The bottom–up approach involving the scientists

[60] WHO, Department of Communicable Disease Surveillance and Response, 'Transport of infectious substances; Background to the amendments adopted in the 13th revision of the United Nations Model Regulations guiding the transport of infectious substances', Global Health Security, Doc. WHO/CDS/CSR/LYO/2004.9, 2004, <http://www.who.int/csr/resources/publications/WHO_CDS_CSR_LYO_2004_9/en/>; and United Nations, *Recommendations on the Transport of Dangerous Goods: Model Regulations*, 13th revised edn, 2003, <http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html>.

[61] European Commission, *The Rules Governing Medicinal Products in the European Union, Vol. 4: Good Manufacturing Practices, Medicinal Products for Human and Veterinary Use*, 1998 edn, Update of legal references in August 2004, <http://pharmacos.eudra.org/F2/eudralex/vol-4/pdfs-en/intr4en.pdf>; WHO, *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Vol. 2, Good Manufacturing Practices and Inspections*, <http://www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp/gmpintro.html>; and US Department of Health and Human Services, Food and Drug Administration, 21 CFR Parts 808, 812 and 820 Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule, *Federal Register*, no. 52601 (7 Oct. 1996).

[62] OECD, Series on principles of Good Laboratory Practice and compliance monitoring, no. 1, ENV/MC/CHEM(98)17, 26 Jan. 1998, <http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1_1,00.html>.

[63] World Health Organization, *Laboratory Biosafety Manual* (note 5).

directly is essential.[64] In many states the national regulations for pathogenic micro-organisms and toxins require those engaged in working with such materials to be appropriately qualified and trained. An ethical review process might well make a positive contribution to security and oversight of pathogenic micro-organisms and toxins.[65]

Many facilities today have well developed bio-safety rules to protect their personnel. National rules and regulations are common. The WHO has also issued guidelines and recommendations.[66] In many developing countries and for states of the FSU there is an urgent need to enhance bio-safety practices in general. The recent (2003–2004) cases of accidental releases of SARS are instructive in that they were due not to problems with facility design and containment engineering or failures in equipment used but to a failure of laboratory personnel to follow bio-safety procedures and practices.

The science community voluntarily conforms to codes of conduct on issues such as research ethics and professional conduct. Self-regulation has worked well in these and other areas. Initiatives are under way to apply a self-regulatory approach in the context of balancing scientific freedom and bio-security. This approach has to be complemented by a regulatory framework.[67] Most scientists already work under codes of conduct as regards laboratory standards and safe working practices, but they are often unaware of treaties such as the BTWC and their implications for their work. Education and training of individuals are therefore important in order to raise awareness. Mandatory courses and training sessions on ethics and codes should be taught at universities and other educational establishments. Fortunately, once formulated, a sound strategy for biological security will help sustain itself because many of its core provisions will benefit public health even apart from acts of bio-terrorism.

Legal and regulatory systems

Many countries are reviewing their existing health and safety legislation from the point of view of whether additional provisions are required to prevent unauthorized access to or acquisition of the agents of concern. A small number of countries so far (France, the UK and the USA) have legislation that specifically addresses bio-security. Legislation is important, as is effective coordination in governments and internationally between the various government agencies involved.[68]

[64] Averre, D., Luongo, K. N. and Martellini, M., 'Advancing bio threat reduction: Findings from an international conference', Landau Network Centro-Volta and Russian American Nuclear Security Advisory Council, 2004.

[65] Pearson, G. and Dando, M., 'Maximizing the security and improving oversight of pathogenic microorganisms and toxins', Strengthening the Biological Weapons Convention, Briefing Paper no. 5, University of Bradford, Department of Peace Studies, July 2003; and Pearson, Graham S., 'National measures to establish and maintain the security and oversight of pathogenic microorganisms and toxins', Briefing Paper No. 4 (Second Series), University of Bradford, Department of Peace Studies, Apr. 2003.

[66] World Health Organization, *Laboratory Biosafety Manual* (note 5).

[67] OECD, International Futures Programme (IFP), 'Promoting responsible stewardship in the biosciences: Avoiding potential abuse of research and resources', Chairman's Summary, Frascati, Italy, 17–19 Sep. 2004.

[68] NATO Workshop, Presented in the absence of Ambassador Tibor Tóth by the co-Director of the Workshop, Graham S. Pearson; United Nations, 'The design of national mechanisms to maintain security and oversight of pathogenic microorganisms and toxins', Working paper prepared by the United Kingdom, Meeting of Experts, Geneva, 18–29 Aug. 2003, BWC/MSP.2003/MX/WP.7/rev.1, 15 July 2003; United Nations, 'Security of dangerous pathogens and toxins', Working paper prepared by USA, Meeting of Experts, Geneva, 18–29 Aug. 2003, BWC/MSP.2003/MX/WP.5, 4 July 2003; United Nations, 'Preventing unauthorized acquisition of pathogenic agents and toxins: A legal patchwork', Working paper by the Netherlands, Meeting of Experts, Geneva 18–29 Aug. 2003, BWC/MSP.2003/MX/WP.14, 30 July 2003; United Nations, 'Specific measures taken by the United States relevant to security of dangerous pathogens and toxins', Working Paper prepared by the United States, Meeting of Experts, Geneva, 18–29 Aug. 2003, BWC/MSP.2003/MX/WP.6, 4 July 2003; and US legislation: the Biological Weapons Anti-Terrorism Act of 1989 (Public Law 101-298), Chemical and Biological Weapons Control and Warfare Elimination Act of 1991 (Public Law 102-182, Title III), the Uniting and Strengthening America by Providing

An effective system will cover both national regulations and an oversight mechanism. The regulations should include for example a dedicated national authority, a list of dangerous pathogens and toxins listed according to bio-security risk and list of facilities handling or storing such agents, a requirement to implement physical security measures, measures to limit access to listed agents and penalties if regulations are not followed. To enable government oversight also of non-governmental facilities, for example, a register or licensing system of facilities and/or personnel handling or transporting listed agents, powers to inspect facilities and the possibility to review security measures implemented will be necessary. Monitoring such an overview could be part of the task of a national authority responsible for the implementation of the BTWC.

International approaches

It is essential to establish international standards for safe and secure handling of pathogens and toxins in diagnostic and research laboratories, health care facilities, pharmaceutical facilities and in transport. There are a number of initiatives on a regional and international level covering the containment of biological agents and of genetically modified organisms. Examples are the September 2003 Cartagena Protocol on Biosafety to the 1992 Convention on Biological Diversity[69] which includes requirements for the provision of information that specifies any requirements for the safe handling, storage, transport and use of living modified organisms (although not for unmodified). The entry into force of the Cartagena Protocol can be seen as part a new common framework.[70] The OECD has been engaged in promoting harmonizing regulations in biotechnology, including health and safety aspects. There is at present no concrete proposal for a Convention on Physical Protection of Dangerous Pathogens.[71] The BTWC, the Chemical Weapons Convention (CWC) and the Organisation for the Prohibition of Chemical Weapons (OPCW) are also relevant in regard to toxins. According to UNSC Resolution 1540 states are required to report on their legislation in areas relevant for bio-safety and bio-security,[72] which should make it easier to get a broad picture of how many states have this kind of legislation.

Principal EU approaches to bio-safety, bio-security and threat reduction

The importance of joint action in the EU to complement national measures led to the need for health security coordination in the EU through the establishment of a high-level Health Security Committee (HSC) in November 2001, composed of representatives of Member States' health ministries together with the Commissioner for Health and Consumer Protection. This to serve as instrument for cooperation and planning, for countering deliberate releases of biological and chemical agents within the EU, and is assisted by a task force. The BICHAT programme of cooperation in the EU on preparedness and response to biological and chemical agent attacks (health security),

Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) of 2001 (Public Law 107-56), the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) and the Agricultural Bioterrorism Protection Act of 2002 (Public Law 107-188, Title II, Subtitle B).

[69] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, <http://www.biodiv.org>.

[70] See <http://www.biodiv.org/biosafety/protocol.asp>.

[71] Pearson, G. S., 'Return to Geneva: A comprehensive list of measures', Review Conference Paper No. 7, Strengthening the Biological Weapons Convention, University of Bradford, Aug. 2002.

[72] United Nations, Security Council Resolution 1540, 28 Apr. 2004.

drawn up in December 2001, comprised 25 actions.[73] A European Commission advisory group on bio-security also exists and has made an inventory of research in Member States. However, not all Member States seem to be willing to share information.[74] The Commission funds an action programme in the field of public health (2003–2008) that aims to develop mechanisms and build up capacity in Member States and candidate countries to respond to major health threats, including a rapid reaction capability. Research is needed to deepen understanding and enhance the scientific base for EU health policy and of developments in European health systems. It will focus on communicable diseases (the development of an improved control and prevention system at European level), and rare diseases (to improve the understanding of a number of already identified diseases and facilitate the identification of others). Priorities are rapid diagnostics, detection tools, disease and risk assessment models, new vaccines and novel therapeutics, surveillance methods, and periodic appraisal of vulnerabilities.[75]

The European Commission has adopted further decisions[76] to place certain pathogens that might be used in bio-terrorist attacks under specific surveillance in the EU with appropriate case definitions and the development of surveillance schemes and networks for epidemiological surveillance. The Commission facilitates information sharing and mutual consultation of Member States on countermeasures using the EU Early Warning and Response System (EWRS). In this context, the Commission has also set up, jointly with EUROPOL, a training module on interaction between public health and law enforcement to develop understanding of relevant laws and common approaches, using a 'train the trainers' strategy. This health security initiative is now being embedded in a wider effort of emergency preparedness and response.[77] It exchanges information on health-related threats, coordinates health preparedness and emergency response plans and crisis management strategies, raises the alert, communicates rapidly in the event of health-related incidents of EU concern, advises on the management of risk, and facilitates and supports training and the dissemination of good practice and experience. There is also EU support to the WHO disease surveillance system and a process for collaboration on risk assessment. The ECDC was established in Stockholm on 21 April 2004 and inaugurated on 27 May.[78] The centre will be fairly small and will grow to around 300 people in 2010.[79] The health sector has been particularly active in international cooperation. The Commission is a founding and full partner in the Global Health Security Initiative initiated by the G7 and Mexico.

The Health Threat Unit in the European Commission is responsible for chemical, biological and radiological (CBR) terrorism surveillance and warning. It has established seven working groups, including one for preparedness and response planning, incident

[73] Commission of the European Communities, 'Programme of cooperation on preparedness and response to biological and chemical agent attacks [Health Security]', Luxembourg, Doc. GFS D(200) GG, 17 Dec. 2001, <http://europe.eu.int/comm/health/ph_threats/Bioterrorisme/bioterrorisme_en.htm>; and 'Health ministers wish to strengthen the network approach in response to bioterrorism threat', *Eurosurveillance Weekly*, 5:011129 (2001).

[74] Flåoyen, A., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay, Brussels, 25 Jan. 2005.

[75] '8.1 Policy orientated research', URL ftp://ftp.cordis.lu/pub/fp6/docs/wp/sp1/h_wp_200201_en.pdf>.

[76] European Commission Decision 2003/534/EC of 17 July 2003; and Commission of the European Communities, Communication from the Commission to the Council and the European Parliament on Cooperation in the European Union on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security), Brussels, 2 June 2003, Doc. COM(2003) 320 final.

[77] Gouvras (note 28).

[78] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control. See also the list of priorities at note 1.

[79] 'Europe's new disease control chief faces tough challenge', *Financial Times*, 19 May 2005, p. 4.

investigation and sampling, and cooperation between laboratories.[80] Communicable diseases caused by potential bio-terrorism acts will be monitored by the EU Rapid Alert System through a complex network of rapid alert systems, including national surveillance systems and WHO systems. The Health Emergency Operations Facility coordinates and evaluates data and conducts follow-ups. Information and warnings are then sent to Member States via BICHAT, which also conducts follow-ups, coordinates information and deploys emergency teams if appropriate.

A common EU view on the biological threat would be beneficial for setting the needs for enhanced pathogen bio-security. Standards for bio-safety exist in the EU and the WHO has developed international guidelines in its manual. In contrast, where bio-security is concerned there are no common standards in the EU and no real agreement on how the term is defined.

The EU is developing a more coordinated and cross-pillar approach to the fight against terrorism. It will also ensure full implementation of the EU Health Security Strategy and chemical, biological, radiological and nuclear (CBRN) programme.[81] In 2002 a joint Commission and Council programme was adopted to improve preparedness for CBR terrorism with initiatives in the areas of research, public health, agriculture, energy, nuclear, transport and the environment.[82] Life sciences with biological research as one key element will be central in the EU's new programme of security research.[83] In fields directly related to biological and chemical terrorism, the 6th Framework Programme's Scientific Support to Policies activities cover 'Civil protection (including biosecurity and protection against risks arising from terrorist attack) and crisis management'.

The European Council at Thessaloniki, 19–20 June 2003, adopted a declaration on non-proliferation of WMD and then an EU strategy against proliferation of WMD.[84] The strategy is aimed at preventing third countries and terrorists acquiring CBRN materials and their means of delivery by seeking an effective multilateral response to this threat (including the multilateral non-proliferation treaties). This will be done by making use of all available EU instruments to deter, halt and if possible prevent proliferation, including implementing export control policies, adding non-proliferation clauses in agreements with third countries, and enhancing the security of proliferation-sensitive materials, equipment and expertise. The EU approach is guided by:

[80] Thinus, G., 'Health security cooperation in the European Union', Paper presented at the International Conference on Biosafety and Biorisks, Lyons, 2–3 Mar. 2005, <http://www.upmc-biosecurity.org/pages/events/biosafety/speakers/thinus/thinus.html>.

[81] Council of the European Union, 'EU plan of action on combating terrorism', Doc. 10586/04, Brussels, 15 June 2004.

[82] Council of the European Union, 'Adoption of the programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats', DG I, 14627/02, Brussels, 21 Nov. 2002; and Council of the European Union, 'EU solidarity programme on the consequences of terrorist threats and attacks (revised/widened CBRN Programme) – Adoption', Doc. 15480/04, Brussels, 1 Dec. 2004.

[83] European Commission, 'New Framework Programme launched: A fact sheet', 2004; Stafford, N., 'Bioresearch key for EU defence', *The Scientist*, 22 Oct. 2003, <http://www.the-scientist.com>; Commission of the European Union Communities, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, Security Research: The Next Steps, COM(2004) 590 final, Brussels, 7 Sep. 2004; and European Commission, Decision of 3 February 2004 on the implementation of the Preparatory Action on the Enhancement of the European industrial potential in the field of security research (2004/213/EC), *Official Journal of the European Union*, L67/18 (5 Mar. 2004).

[84] Council of the European Union, 'Proliferation of weapons of mass destruction: Report on the follow up to the Thessaloniki European Council and on the state of execution of the Action Plan for the implementation of the Basic Principles for an EU Strategy against Proliferation of Weapons of Mass Destruction', Brussels, 12 Sep. 2003; and Council of the European Union, 'EU strategy against proliferation of weapons of mass destruction', Doc. 15708/03, Brussels, 10 Dec. 2003.

- the conviction that a multilateral approach to security, including disarmament and non-proliferation, provides the best way to maintain international order and hence our commitment to uphold, implement and strengthen the multilateral disarmament and non-proliferation treaties and agreements;
- the conviction that non-proliferation should be mainstreamed in overall policies, drawing on all the resources and instruments available to the EU;
- the determination to support the multilateral institutions charged with verifying and upholding compliance with these treaties;
- the view that increased efforts are needed to enhance consequence management capabilities and improve coordination;
- the commitment to strong national and internationally-coordinated export controls on dual-use items;
- the conviction that the EU in pursuing effective non-proliferation should be forceful and inclusive, and must contribute actively to international stability; and
- the commitment to cooperate with partners who share the same objectives.

The issue, the scope of mission and the possible modalities of a monitoring centre for the WMD Strategy are being discussed.[85] Cooperation between the public health, occupational health and safety and non-proliferation structures should be reinforced. An initiative will be taken in order to promote dialogues, first, with industry in the EU countries, with a view to raising the level of awareness of problems related to WMD, and, second, between the European and US industries, in particular in the biological sector. EU CTR programmes with other countries should be reinforced, should provide support to non-proliferation and disarmament, and should help to strengthen the control and security of sensitive materials, facilities and expertise. There will be new financial perspectives in the period after 2006, when the creation of a new mechanism to finance non-proliferation and disarmament of WMD should be envisaged.

The EU supports the BTWC, and the need for an international verification capability regarding BW is identified in the WMD Strategy as an EU objective.[86] The examination of information provided by Member States on their bilateral assistance programmes led to the conclusion that there is scope for EU initiatives in the field of BW, for example, a programme of assistance to states in need of technical knowledge in order to ensure the security and control of sensitive material, facilities and expertise. In October 2003, Javier Solana, the EU High Representative for the Common Foreign and Security Policy, appointed a Personal Representative for the non-proliferation of WMD in order to coordinate, help implement and further develop the EU WMD Strategy. The Personal Representative has put forward suggestions in the context of her lists of priorities.[87]

The role of the UN Security Council, as the final arbiter on the consequences of non-compliance, needs to be effectively strengthened, not least in the biological area, and the EU places particular emphasis on a policy of reinforcing compliance with the multilateral treaty regimes. Such a policy must be geared towards enhancing the detection of significant violations and strengthening enforcement of the prohibitions and norms established by the multilateral treaty regime, including by providing for criminalizing violations committed under the jurisdiction or control of a state.

[85] Council of the European Union (note 1).

[86] Council of the European Union, 'A Common Position on the universalisation and reinforcement of multilateral agreements in the field of non proliferation of WMD and their means of delivery', Doc. 2003/805/CFSP, Brussels, 17 Nov. 2004.

[87] Council of the European Union (note 1).

In a first report on the implementation of the WMD Strategy in December 2004, strong support for UN Security Council Resolution 1540 is expressed, and the EU will take the lead in efforts to strengthen regulations on trade in material that can be used for the production of BW and in supporting national implementation of the BTWC. The report states that in connection with the BTWC there might be scope for assistance programmes: a group of experts could be convened that could also be useful in the context of the development of bio-security and bio-safety standards; and it also mentions that the possibility of setting up a scientific institute to redirect the knowledge of former weapons scientists coming from regions other than the former Soviet Union is to be examined.[88] Such an institute would require substantial funds for an extended period (eight to 10 years) and, in the light of the experience of the ISTC, €150 million would be required to set up a new institute over a minimum five-year period. Alternatively, a mechanism could be set up to allocate critical expertise and skills to European public and private industries, possibly through a scheme by which R&D funds from the industrial and private sector could be used to employ former WMD scientists.

It has been decided to include WMD provisions in future cooperation agreements with third countries, and steps have been taken with a number of countries and regions in this regard.[89] The non-proliferation clause adopted on 17 November 2003 requests full compliance with and national implementation of obligations undertaken by parties under multilateral frameworks, and fosters steps for further adherence to other relevant international instruments.

Russia is identified in the WMD Strategy as a key partner for cooperation. The EU is also a 'participant' in the Association of Southeast Nations (ASEAN) Regional Forum (ARF); exchanges of views on non-proliferation issues are a major part of its work.[90] In 1999, when the EU agreed on a Joint Action to support disarmament in Russia,[91] biological projects were not included under this action. However, the EU agreed to support the Non-proliferation and Disarmament Cooperation Initiative (NDCI), and this indicates the strong commitment by the EU to basing efforts in Russia on a positive, collaborative approach. Projects in the biological area funded through the ISTC in Moscow require participation by former weapons scientists. The ISTC has emerged as the main multilateral source of funding for the biological area, and at the NDCI conference in London in 2004, in the biological session, it was pointed out that future support should have high priority in the area of bio-safety/bio-security.[92] Many biological facilities must reduce their size and activities, which will result in facilities and equipment not being used. Bio-security should already be given high priority, and this should be put forward at the next Global Partnership meeting. A master plan for the long term where all partners could better see how their and other partners' support fits in to the whole bio-security picture could be valuable.

The Technical Assistance to the Commonwealth of Independent States (TACIS) programme is the EU's assistance programme for the newly independent states of the FSU on both a national and regional basis. TACIS focuses some assistance on areas

[88] Council of the European Union (note 1).

[89] European Union, 'Non-proliferation clause to be included in agreements with third countries', Countering proliferation of weapons of mass destruction, <http://ue.eu.int/uedocs/cmsUpload/st14997.en03.pdf>.

[90] 'Asia–Pacific ministers target missiles, biological attacks', Agence France-Presse, 18 Nov. 2004.

[91] *Official Journal of the European Communities*, L331/11 (Dec. 1999).

[92] UK Department of Trade and Industry, 'NDCI, Non-proliferation and Disarmament Co-operation', 2004, <http://www.dti.gov.uk/energy/nuclear/fsu/ndci_event_con04.shtml>.

with relevance for non-proliferation and disarmament.[93] However, only 1–2 per cent of the total budget has supported disarmament and non-proliferation, the most important support being to finance the EU contribution to the ISTC and the STCU, and within that amount relatively little can be identified as relevant to bio-security.

The International Association for the Promotion of Co-operation with Scientists from the New Independent States of the Former Soviet Union (INTAS) is an independent international association formed by the European Community, EU Member States and like-minded countries to promote East–West scientific cooperation between INTAS members and INTAS partner countries from the NIS. INTAS works in close cooperation with the European Community and plays an important bridging role between the NIS and the European Community, especially through activities relating to the EU Framework Programmes for Research and Technological Development. INTAS supports fundamental and applied research in all fields of science, including the life sciences. Its activities help to open the European Research Area (ERA) to the NIS by supporting scientific cooperation that is fully consistent with the objectives of the Framework Programme decided by the European Parliament and the Council.[94]

The EU has taken some steps to enhance cooperation in the area of threat reduction with Russia since 1999.[95] In June 2003 the European Council agreed to extend the Common Strategy on Russia for one year, but it has not been considered necessary to extend it since, and the immediate priority is seen as developing the four Common Spaces agreed with Russia in St Petersburg in May 2003.[96] As noted by the 12th EU–Russia Summit held in Rome on 6 November 2003, cooperation will continue to combat terrorism in all its forms and to prevent the proliferation of WMD. The examination of information provided by Member States on bilateral assistance programmes to Russia and the NIS leads to the conclusion that EU Member States are not very active in the biological area, and consideration should be given to developing new initiatives.

Member states are showing interest in enhancing their efforts in the biological area but still seem to be unwilling to fund large projects in this area directly.[97] In 2005 the UK holds the G8 Presidency, and one of the two areas the UK will focus on is combating the threat of bio-terrorism. The UK will also work with other donors to develop biological redirection programmes, including the ongoing one in Georgia involving an anti-crop institute.[98] The UK plans further biological redirection projects but the budget so far is very modest.[99] France committed €5 million for bio-security and bio-safety in Russian biological facilities in 2004.[100] For some years Sweden has had an interest in

[93] UK Foreign and Commonwealth Office, Department of Trade and Industry and Ministry of Defence, 'The G8 Global Partnership: Progress during 2004 on the UK's programmes to address nuclear, chemical and biological legacies in the former Soviet Union', Dec, 2004, section 6, TACIS, p. 73, <http://www.dti.gov.uk>.

[94] European Union, Co-operation activities with Russia and the other NIS countries will be carried out in particular through the INTAS structure, set up jointly by the Community and the Member States, Decision no. 1513/2002/EC.

[95] Council of the European Union, 'Report of the implementation of the Council Joint Action 1999/878/CFSP of 17 December 1999 establishing a European Union Cooperation Programme for Nonproliferation and Disarmament in the Russian Federation', Doc. 13154/01, Brussels, 23 Oct. 2001; and Council of the European Union, Decision 2003/874/CFSP of 8 December 2003 implementing Joint Action 2003/472/CFSP with a view to contributing to the European Union cooperation programme for non-proliferation and disarmament in the Russian Federation, *Official Journal of the European Union*, L326 (13 Dec. 2003).

[96] Council of the European Union, 'Relations with Russia: Council report on the implementation of the Common Strategy of the European Union on Russia', Doc. 10293/04, Brussels, 8 June 2004.

[97] Roffey *et al.* (note 38).

[98] UK Foreign and Commonwealth Office, Department of Trade and Industry and Ministry of Defence (note 93).

[99] Presented at the NDCI, London 2004.

[100] UK Foreign and Commonwealth Office, Department of Trade and Industry and Ministry of Defence (note 93), section 5, France. p. 63.

the biological field and funded some small projects,[101] and a Finnish–Russian Joint Biotechnology Laboratory has been operating in Turku, Finland, but the activities have been very limited due to lack of funding and have consisted mainly of advice to and small projects with Russian biotech businesses. The European Commission has a project involving several Member States with the Vector institute to develop Diagnostic methods for orthopoxviruses which has been discussed for some time. This project has been initiated through the European Commission Directorate for Public Health and Risk Assessment.[102]

Russia, bio-security, bio-safety and threat reduction

In Russia it is illegal to be, and also to provide any form of support to actors that are reliably believed to be, involved in the development, production, acquisition, sale, transfer (including export) or use of chemical or biological weapons.[103] Laws have been adopted in Russia, and are enforced, to prohibit any non-state actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes, as well as attempts to engage in any of the forgoing activities, participate in them as an accomplice, or assist or finance them.[104] There is legislation to prevent any action in violation of the provisions of the BTWC.[105]

Major structural and organizational changes were carried out in the spring of 2004 throughout the Russian government ministries and agencies. The Munitions Agency, which had national responsibility for the biological and BTWC area, was placed in a new Federal Agency for Industry, which reports to the Ministry of Energy and Industry.

Russia has made significant progress concerning bio-safety measures for work with dangerous pathogens and at facilities, even if much still remains to be done. The Inter-Agency Committee on Problems of Genetic Engineering Activity, established in 1997, has introduced bio-safety measures. Together with the Inter-Agency Committee on Biotechnology, from 2002 coordination and recommendations are given. The Ministry of Industry, Science and Technologies has been responsible for questions concerning bio-safety including genetically modified organisms (GMO) and their registration since

[101] UK Foreign and Commonwealth Office, Department of Trade and Industry and Ministry of Defence (note 93), section 5, Sweden, p. 65.

[102] George Gouvras, Personal communication, European Commission, Directorate Public Health and Risk Assessment, Health and Consumer Protection Directorate-General, 23 May 2005.

[103] United Nations Security Council, 'Annex to the note verbale dated 26 October 2004 from the Permanent Mission of the Russian Federation to the United Nations addressed to the Chairman of the Committee Report of the Russian Federation on the implementation of Security Council resolution 1540 (2004)', UN document S/AC.44/2004/(02)/14, 2 Nov. 2004; and United Nations, 'Working paper submitted by the Russian Federation: Answers to the questionnaire on national legislation ensuring compliance with the Convention on the Prohibition of Biological and Toxin Weapons', BWC/MSP.2003/WP.6, 11 Nov. 2003.

[104] Federal Act of the Russian Federation No. 63-FZ of 13 June 1996 On the Implementation of the Penal Code of the Russian Federation contains articles penalizing violations of international obligations in the field of non-proliferation of WMD.

[105] The main regulatory and legal instruments in that field which ensure Russia's compliance with its obligations under the convention (signed in 1972 and ratified in 1975) are as follows. Decree of the President of the Russian Federation no. 390 of 11 Apr. 1992 On Ensuring Implementation of International Obligations in the Field of Biological Weapons. The legislative and normative basis for implementing the BTWC, including criminal liability for infringement of the convention's provisions, has been established. The Criminal Code, which entered into operation on Jan. 1997, includes the following articles: article 236 'Violation of sanitary and epidemiologic rules'; article 248 'Infringement of safety rules when handling microbiological either other biological agents and toxins'; article 249 'Violation of veterinary rules and rules, established for fighting with plant diseases and pests'; article 355 'Production or distribution of mass destruction weapon'; article 356 'Application of inhibited means and methods of warfare'; article 188 'Smuggling'; and article 189 'Illegal export of technologies, scientific and technical information and services, which can be used in the development of mass destruction weapon and means of its delivery'.

2001.[106] Since April 2004 the Ministry of Industry and Energy has had this same responsibility. Regulations have been adopted concerning work with dangerous pathogens, for which a licence is required.

In Russia pathogenic organisms are divided into four classes depending on the level of hazard. All facilities are divided into categories depending on the substances they contain, and sanitary, hygienic, anti-epidemic and physical protection measures being taken. Pathogenic organisms are stored in culture collections under strict control by the Sanitary and Epidemiological Inspectorate.[107] Currently Russia possesses all the known dangerous pathogens that could be used for manufacturing BW, including smallpox.[108] Biological facilities are subordinated to different ministries: the Ministry of Health controls the activity of institutes and enterprises dealing with pathogens dangerous to human beings, and the Ministry of Agriculture those dealing with pathogens dangerous for plants and animals. Genetic engineering is under supervision of the Ministry of Industry, Science and Technology.

The Russian Government has a policy of not giving much information on biological facilities concerning workforces, agents and so on as being too transparent might provide potential terrorists with sensitive information. There is a list of organizations that have been authorized to possess specialized collections of micro-organisms of Hazard Groups I-IV. On the list that was published as an annex to the sanitary rules issued by the State Committee of Sanitary Inspection of Russia (Gossanepidnadzor) in 1995 there were 17 such institutions. Sanitary rules exist for the storage, transfer and transportation of micro-organisms according to the four risk groups.[109] These collections are declared to be national and cannot be privatized. Russia also has export control legislation in line with the Australia Group.[110] Very little attention has been given in Russia to bio-security issues, although now this might be changing.

In Russia bio-security is referred to as the deficiencies in the protection against bio-terrorism, in a similar manner to the USA. The term 'biological security' in Russia can sometimes mean bio-security and bio-safety, which might be confusing. In December 2003 the Russian Security Council examined a concept for biological and chemical security but without financing its implementation. The Ministry of Health and Social Development has prepared a federal programme on bio-security and indicated that Russia needs to create an effective bio-security system.

[106] See <http//:www.oecd.org/document/30/0,2340,en_26493_2509342_1_1_1,00.html>, 24 Oct. 2003.

[107] 'Russian centers working with pathogens unrelated to bio-arms', Interfax News Agency, 11 Mar. 2004; and 'Moscow daily notes US leadership "alarmed" at Russian bioweapons facilities', BBC Monitoring International, 13 Mar. 2004.

[108] Shitikov, A., 'New directions of the Global Partnership programme', *Yaderny Kontrol*, no. 1 (spring 2005), pp. 159–71.

[109] Safety Work with Microorganisms of Hazard Group III-IV and Helminthes. (1999). Sanitary Rules 1.2.731-99; Federal Center of the State Committee of Sanitary Inspection, Russian Ministry of Public Health, Moscow; see also <http://www. medinfo.ru/price95_6.shtml>; and Kiritchenko, E., 'The human component of bio-threat reduction', Paper presented at the International Workshop on Building Global Partnership for Bioproliferation Prevention: Current Status and Future of Russian Biotechnology, Como, Italy, 17–18 Nov. 2003.

[110] Federal Law of the Russian Federation no. 183 of 18 July 1999 and the Federal Law On Export Control laid a legal basis for export controls. The Decree of the President of the Russian Federation no. 1004 of 8 Aug. 2001 approved the List of Pathogens of Human Being, Animals and Plants, Genetically Changed Microorganisms, Toxins, Equipment and Technologies, Liable to Export Control. Resolution of the Government of the Russian Federation no. 634 of 29 Aug. 2001 On Approval of the Provisions on Control over External Economic Activity in Respect of Pathogens of Human Being, Animals and Plants, Genetically Changed Microorganisms, Toxins, Equipment and Technologies introduced guidelines of appropriate export control regime. The 1999 law defined more precisely the sphere of control and codified such terms as 'foreign economic activity'. The state tried to place all the channels of international technology transfers under control; particular attention was paid to communication by electronic mail and Internet. List of human, animal and plant pathogens, genetically modified organisms, toxins, equipment and technology subject to export control, Ukaz no. 1004, *Rossiyskaya Gazeta*, 11 Aug. 2001, p. 15.

Supporting chemical and biological security is one of the most important ways of strengthening Russia's national security.[111] The Russian President is to maintain overall supervision of the implementation of these fundamental principles. The programme will cover such aspects as the coordination of scientific research, the creation of a system for the early identification of dangerous pathogens, refurbishing scientific centres with new equipment, enhancing bio-security and bio-safety of facilities containing large quantities of dangerous pathogens, the creation in collaboration with the customs service of a more effective system of control on the borders and on Russia's entire territory, and the provision of new equipment to medical centres and epidemiology control centres.[112] A governmental commission on biological and chemical security has been set up under the leadership of the Minister for Health and Social Development. This commission is to include representation from all the security ministries, as well as the ministries of science and education and agriculture, at no lower than deputy minister level.[113] A resolution has clarified which agencies are responsible for ensuring national bio-security and chemical security in Russia. From 2006 the Ministry of Health and Social Development with other federal agencies should deliver an annual report on progress made towards reducing the negative effects of dangerous biological agents and chemical substances of natural or man-made origin on the population, the bio-sphere and man-made installations, with proposals of perfecting the state system of biological and chemical security in Russia. Other ministries involved are Defence, Foreign Affairs, Emergencies, Natural Resources, and Industry and Energy.[114]

A growing number of facilities in Russia are working close to their limit or have passed it and are in a state of decline in terms of training, equipment maintenance and physical protection, or are violating the rules for the storage and handling of facilities and hazardous materials. There are deficiencies in government oversight and in the regulations (e.g. on safety). The objective is to create a state system for countering biological and chemical threats and handling emergency situations, and improve the system of training, retraining and certification of highly qualified personnel. Criteria are to be developed for the categorization of facilities by risk level and an inventory of facilities is to be carried out, including a list of critically important facilities.[115]

President Putin has stated that the goal of terrorists is to get access to WMD, and bio-terrorism has become a reality, requiring adjustments to national defence policies.[116] Russia has taken some concrete measures to counter the bio-terrorism threat, including setting up two centres against bio-terrorism, one in Volgograd, and one for the diagnosis and treatment of dangerous and exotic diseases under the Ministry of Defence at Sergiyev Posad.

[111] 'Fundamental principles of state policy on chemical and biological security of the Russian Federation in the period to 2010 and the long term' (unattributed article, FBIS Translated Text, FBIS-SOV-2004-0408), *Rossiyskaya Gazeta* (Moscow), 7 Apr. 2004.

[112] Warrick, Joby, 'Russia denies US access on bioweapons', *Washington Post*, 8 Sep. 2002; G8 Action Plan on Nonproliferation, <http://www.g8usa.gov/documents.htm>; and <http://www.informeco.ru/stat.php?stat=231>.

[113] 'Public Health Chief Onishchenko says Russian biosecurity "cause of concern"', *Nezavisimaya Gazet*a (Moscow, in Russian), 15 Oct. 2004, in FBIS-SOV-2004-1015, 20 Oct., 2004; and 'Russia sets up commission to fight biological threat', Monnews, 14 Feb. 2005, <http://www.mosnews.com/news/2005/02/14/biodefence.shtml>.

[114] 'Russian government tightens grip on country's biological, chemical security', BBC/ITAR TASS, 19 May 2005, <http://www.sgpproject.org/Personal%20Use%20Only/RUCWBWSecurity.html>.

[115] Kobyakov, D. and Orlov, V. A., 'Global partnership: What's next?', Report prepared for the Geneva Centre for Security Policy, Apr. 2005, <http://www.sgpproject.org/publications/KobyakovOrlovApril2005GPWhatisnext.pdf>.

[116] [Putin felt the threat of bioterrorism] (in Russian), <http://www.nns.ru/archive/chronicle/2001/11/12.html>.

Cooperation between Russia and USA in the fight against terrorism[117] plays an important role in achieving the long-term non-proliferation goals.[118] In 2001 their two presidents agreed to combat bio-terrorism and issued a joint statement: Russia and the USA will work together on means for countering the threat of bio-terrorism, now faced by all nations, and on related health measures, including preventive ones, treatment and possible consequence management. The security of materials, facilities, expertise and technologies that can be exploited by bio-terrorists should be enhanced, and the presidents confirmed a strong commitment to the BTWC.[119] However, at the practical level cooperation between the two countries has remained low.[120]

Although the Russian Government has re-confirmed that it sees threat reduction and disarmament support as important elements in its security policy, Russia has not supported Global Partnership initiatives aimed at reducing threats in the biological area. Its official position remains that Russia has not inherited any BW capacity from the Soviet Union. Russia maintains that it does not have facilities for the production of biological and toxin weapons and observes its international obligations strictly. At the same time former Soviet BW scientists, screened by the Russian Government, are financed through international threat reduction programmes such as the ISTC, where scientists declare participation in former weapons programmes in order to receive grants.[121] One example of the difficulties involved, concerning the Ministry of Defence, is Kirov-200 at Strizhi, a former BW production plant that was part of the Institute of Microbiology in Kirov. It is a special case since it is one of the former BW facilities under the Ministry of Defence that was transferred to the Ministry of Education in 2001.[122] The discussions on conversion, potential cooperation and foreign investments between the US and other potential governments have not made much progress since 2000 and are still ongoing. According to the head of the institute in Sergiyev Posad, the system of monitoring biological substances in scientific institutions of the Russian Ministry of Defence rules out the potential threat of terrorist organizations making BW. There are sufficient forces and means to prevent individuals from entering laboratories without permission and stealing biological materials from institutions.[123]

The early assumption that there would be a mass exodus of weapons scientists from Russia has proved wrong, even if many have left, at least for some years. Instead, the risks of proliferation of know-how come from inside as scientists are approached for information, technology or strains. There are also very few, if any, cases of prosecution of export control violations in Russia.[124] In the mid-1990s fears were raised that

[117] The Russian Federal Security Service (FSB) has compiled a list of 15 Russian and international organizations officially deemed terrorist organizations by the Russian Government. At least 7 of them are on a similar list compiled by the USA. Al-Qaeda is one of them. The list was handed over to the Prosecutor-General's office in Feb. 2003, according to *Jane's Intelligence Review*, Mar. 2003, p. 3.

[118] In Mar. 2003 Russia undertook some organizational changes by which parts of the signals intelligence agency (FAPSI) and the Federal Border Troops were merged with the FSB. Among other things these changes were made to strengthen FSB's capabilities to fight terrorism and drug trafficking. See *Kommersant*, 12 Mar. 2003, pp. 1, 3; and *Nezavisimoye Voennoye Obozreniye*, no. 4, (7–13 Feb. 2003), p. 7.

[119] Joint Statement by President George W. Bush and President Vladimir V. Putin on Cooperation against Bioterrorism, 13 Nov. 2001.

[120] Warrick (note 112); and 'G8 Action Plan on nonproliferation' (note 112).

[121] Roffey *et al*. (note 38).

[122] Order about the transfer of facilities of the cantonment No. 992 of the Russian Ministry of Defence to the Vyatka State Technical University, Ministry of Education, no. 451, 25 Aug. 2000.

[123] 'Russian military warn of bioweapons attacks', ITAR-TASS (Moscow, in Russian), 1103 GMT, 29 Apr. 2004, BBC Monitoring International, 29 Apr. 2004.

[124] Hoffman, D., 'Where have Russian arms scientists gone?', *Salt Lake Tribune*, 24 Jan. 1999.

improved means of modern telecommunications could offer the possibility to communicate with the outside world without physically leaving Russia (e.g. by e-mail).[125]

It has been proposed that Russia should expand cooperation to other countries than the USA and the UK, such as Canada, Germany, France, Sweden and Switzerland, in the biological area. For Russia, fighting infectious diseases and improving preparedness against natural or deliberate outbreaks are priorities. Russia could have much to offer in the areas of diagnostics and vaccine development. One step would be to establish common standards for bio-safety and bio-security.[126]

US threat reduction programmes in the biological area

The USA, the most important donor, has been devoting *c*. $100–$120 million per year for the past several years to biological threat reduction in the FSU.[127] In the mid-1990s the United States began engaging biological research and production centres throughout the FSU in four kinds of cooperative project aimed at preventing the proliferation of BW capabilities:[128]

- collaborative research projects to prevent former BW scientists from selling their expertise to terrorist groups or proliferating states;
- bio-safety enhancement projects intended to make facilities safe places to work;
- bio-security projects to consolidate and restrict access to pathogens; and
- dismantlement projects to target excess infrastructure and BW equipment at facilities for permanent dismantlement.

The US programme is described in the annex to this paper.

The science centres

The ISTC, founded in 1992, has emerged as the main multilateral source of funding for the biological area. Some biological projects have also been funded through the STCU. The ISTC and STCU focus on all categories of former Soviet WMD scientists. They provide Russian and NIS weapons scientists and engineers with opportunities to redirect their talent to peaceful activities and integrate into the world scientific community, support fundamental and applied research, and support the transition to the market economy. Their activities in the field of bio-threat reduction and bio-security, as well as efforts to redirect Iraqi scientific knowledge and expertise, are described in the annex to this paper.[129]

The Global Partnership against the Spread of Weapons and Materials of Mass Destruction

The Global Partnership was launched at the G8 summit in Kananaskis, Canada in 2002. The statement issued by the G8 leaders at that summit recorded that the G8 will support

[125] Cooperman, A. and Belianinov, K., 'Moonlighting by modem in Russia', *US World & News Report*, 17 Apr. 1995.

[126] Kobyakov and Orlov (note 115).

[127] Powers, M., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay, Brussels, 25 Jan. 2005, pp. 65–70.

[128] Coo, M. S. and Woolf, A. F., 'Preventing proliferation of biological weapons: US assistance to former Soviet states', CRS Report to Congress, Library of Congress, Congressional Research Service, Code RL31368, Apr. 2002.

[129] See also background paper 8.

specific cooperation projects, initially in Russia, to address non-proliferation, disarmament, counter-terrorism and nuclear safety issues. The activities of the Global Partnership are described in the annex to this paper.

Curbing the proliferation of BW is an essential element of the Global Partnership.[130] However, while the question of bio-security was debated at Kananaskis, in the end it was not identified as an area of project activity. While for the USA issues like BW were said to remain a very high priority, this view of the importance of the issue is not shared by Russia.[131] The negotiations at the Kananaskis summit became difficult and because of this there are still some differences of interpretation of the outcome of this summit.

At the Evian summit in June 2003 there was little mention of the biological area except to record that progress had been made with improving the safety and security of biological research facilities.[132] An action plan on capacity-building against terrorism was agreed and a Counter-Terrorism Action Group (CTAG) was created. In the area of health measures were agreed to fight HIV, tuberculosis and malaria and to encourage research on diseases that mostly affect developing countries, and extra funds were created to eradicate polio and improve cooperation against SARS.[133]

At the Sea Island summit in 2004 it was stated that bio-terrorism poses unique, grave threats to the security of all nations and could endanger public health and disrupt economies. A commitment was called for to take concrete national and international steps to expand or, where necessary, initiate new bio-surveillance capabilities to detect bio-terror attacks against humans, animals and crops; to improve prevention and response capabilities; increase protection of the global food supply; and to respond to, investigate, and mitigate the effects of alleged uses of BW or suspicious outbreaks of disease. An appeal was made for commitments made at the Fifth Review Conference of the BTWC (which was recognized as a critical foundation against BW proliferation, including to terrorists) to be realized. Its prohibitions should be fully implemented, including through the enactment of penal legislation.[134]

The G8 has noted that the safety and security of biological research facilities is being improved.[135] In the health area it has agreed on an action plan on HIV vaccine[136] and to eradicate polio.[137]

The G8 members have reaffirmed that proliferation challenges will be addressed worldwide, including by pursuing the retraining of Iraqi and Libyan scientists involved in past WMD programmes. Other recipient candidates—Kazakhstan, Georgia, Uzbekistan and Ukraine—have also been discussed but without agreement being reached (in reality Ukraine is now a recipient[138]). Cooperative bio-safety and bio-security projects

[130] Statement by G8 leaders, Kananaskis Summit 2002, <http://www.g8.gc.ca/2002Kananaskis/kananaskis/globpart-en.sp>.

[131] *Global Partnership Update*, May 2004; and Deffrennes, M., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay, Brussels, 25 Jan. 2005.

[132] G8 Evian Summit, Senior Officials Group Annual Report, presented at the G8 Heads of State and Government, Evian, June 2003, <http://www.g8.fr/evian_report>.

[133] G8 Evian Summit, Chair's summary, 3 June 2003, at <http://www.g8.fr>; and G8 Evian Summit, 'Health: A G8 action plan', June 2003, <http://www.g8.fr>.

[134] Sea Island Summit 2004, G8 Action plan on non-proliferation, June 2004.

[135] G8 Evian Summit, Global Partnership against the spread of weapons and materials of mass destruction, a G8 action plan, June 2003.

[136] 'G-8 action to endorse and establish a global HIV vaccine enterprise', June 2004, <http://fpc.state.gov/fpc/33504.htm>.

[137] 'G-8 commitment to help stop polio forever', June 2004, <http://fpc.state.gov/fpc/33494.htm>.

[138] 'Ukraine selected as next G-8 Global Partnership recipient, US official says', *Global Security Newswire*, 14 Oct. 2005, <http://www.nti.org/d_newswire/issues/2004/10/14/D2519DEB-8CB1-40EDB3C6-4C048577A5B5.html>; and Sehling R. and Nikitin, M. B., 'Ukraine and the Global Partnership: An opportunity for progress', Strengthening the Global Partnership Issue Brief no. 3, Mar. 2005.

are being undertaken mainly by the USA, but also on a very small scale by France, Sweden and the UK, and are being initiated by Canada. So far less than 1 per cent of the funding pledged for the Global Partnership is intended for the biological area.[139]

At the Sea Island summit in 2004 strong support was given for UN Security Council Resolution 1540. It was stated that cooperative bio-safety and bio-security projects were being undertaken.[140] At the G8 Bioterrorism Expert Groups meeting on 30 September 2004 several areas were identified for collaborative action:

- strengthening national and international bio-surveillance capabilities (support the efforts of the Food and Agriculture Organization of the United Nations (FAO) in the International Plant Protection Convention (IPPC) and share information on zoonotic disease surveillance);[141]
- increasing protection of global food production and supply; and
- improving bio-terrorism response and mitigation capabilities. The G8 activities should not duplicate activities taken by the GHSAG.[142]

The USA has called for and proposed a 'plan of action' for cooperation among G8 members on infectious disease surveillance, the creation of a 'clearing house' of emergency health response assets, and improved protection of the food chain.[143] The USA will also initiate a G8 risk assessment workshop in 2005. The generally accepted assessment of the foreign support overall is that the threat reduction and non-proliferation efforts have succeeded to a large degree. According to John Bolton, issues like BW were going to remain a very high priority even if it is not the Russian priority.[144] According to US Senator Richard Lugar, not enough is being done in the biological area, where there are still closed facilities that may not participate in CTR activities.[145] Because of the growing risk of proliferation in the biological area it would be in the interests of the USA, the EU and Russia to find agreement on how to handle the problem of the closed Ministry of Defence facilities. Confidence-building measures should be initiated as a first step. There is also ongoing work in Iraq and Libya, although they are not formally in the Partnership, and a number of other partners are already implementing Global Partnership-type projects in FSU countries other than Russia and Ukraine.[146] Some experts have also proposed adopting cooperative threat reduction mechanisms with India, Pakistan and North Korea.[147]

[139] The reasons for this are discussed in Potter, W., Statement at the International Conference G8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, Moscow, 23 Apr. 2004, <http://www.pircenter.org/rus/club/steno.html>).

[140] 'G8 summit ends with US, France still at odds on Iraq', Agence France-Presse, 11 June 2004; and 'Sea Island Summit 2004', G8 Global partnership *Annual Report*, G8 Senior Group, June 2004.

[141] Additional information on the IPPC can be found at <http://www.ippc.int/IPP/En/default.jsp>.

[142] G8 Bioterrorism Experts Group Meeting, Meeting summary, US Department of State, Washington DC, 30 Sep. 2004.

[143] 'US Ambassador to Russia Alexander Vershbow last week outlined Bush administration proposals to help prevent bioterrorist acts and WMD proliferation', *Global Security Newswire*, 26 Apr. 2004.

[144] Interview with John Bolton in preparation for Sea Island summit, in *Global Partnership Update*, Sea Island Edition, no, 4, May 2004, <http://www.sgpproject.org>.

[145] US Department of State, 'Persistent diplomacy prerequisite for nonproliferation advances: Senator Lugar lists 12 breakthroughs to be pursued for WMD security', International Information Programs, *Washington File*, 11 Aug. 2004.

[146] See <http://www.sgpproject.org/publications/GPUpdates/GPUpdateJan2005.pdf> (accessed 8 Mar. 2005).

[147] Goodby, J. E., Burghart, Daniel L., Loeb, Cheryl A. and Thornton, Charles L., *Cooperative Threat Reduction for a New Era*, National Defense University, Sep. 2004.

WHO epidemiological surveillance, bio-safety and bio-security

The International Health Regulations now being revised are expected to differ from the current regulations in that they emphasize disease outbreaks of global public health significance instead of relying on a list of diseases that member countries must report. This will allow greater flexibility in responding to outbreaks as the WHO may also consult unofficial outbreak reports and ask for cooperation in verifying them. In turn, member countries must provide a timely response to a request from the WHO for disease outbreak verification; otherwise the WHO would be authorized to disclose the information publicly.[148]

A major development for WHO in this field has been the development and implementation of the Global Outbreak Alert and Response Network (GOARN). This function relies on a systematic follow-up of information on suspected outbreaks by providing support to outbreak response activities. GOARN comprises 110 networks that are electronically linked to provide real-time alerts of outbreaks and to support response activities that assist member states. It includes WHO regional offices and collaborating centres/laboratories, military laboratory networks, and the Global Public Health Intelligence Network (GPHIN).[149] The WHO has had an office in Lyons, France, since 2000 with the mission to strengthen capacities, including training in developing countries for the early detection, rapid verification of and response to outbreaks of infectious disease, including preparedness for accidental or deliberate outbreaks.[150] The WHO Bio-safety programme assists member states in achieving uniform bio-risk management since more than three decades including the Bio-safety Advisory Group.[151] Five collaborating centres currently support the WHO's bio-safety activities, situated in Australia, Canada and Sweden, and two in the USA.

The bio-safety programme in the WHO aims to raise bio-safety awareness; reduce the risk of natural or deliberate release of agents of communicable diseases from laboratory facilities and during transport; support adoption and implementation of WHO laboratory bio-safety and bio-security guidelines; and promulgate best bio-safety practices. One activity is to monitor, ascertain, and provide guidance for the containment of smallpox in two official repositories (Vector in Novosibirsk, Russia, and the Center for Disease Control, CDC, in the USA). The WHO has declared that it is satisfied with Russian laboratory safety at the Vektor facility, where strains of smallpox virus are stored.[152]

Failure to follow appropriate bio-safety practices may now be the greatest threat for the reappearance of SARS or polio.[153] The WHO closely works with the FAO and the Office International des épizooties (World Organization for Animal Health, OIE) concerning animal diseases surveillance and response. They also have an import role for preventing and responding to natural or deliberate outbreaks of disease and for

[148] Cosivi, O., 'Preparedness for deliberate epidemics', Paper presented at the International Conference on Biosafety and Biorisks, 2–3 Mar. 2005.

[149] WHO, *Public Health Response to Biological and Chemical Weapons*, 2nd edn, 2002, <http://www.who.int/emc/book2ndedition.htm>; 'WHO's response to the threat of the deliberate use of biological and chemical agents to cause harm', *Weekly Epidemiological Record*, no. 34, 23 Aug. 2002, pp. 281–88, <http://www.who.int/wer>; and WHO Global Outbreak Alert and Response Network, <http://www.who.int/csr/outbreaknetwork>.

[150] WHO Office in Lyons, Department of Communicable Disease Surveillance and Response, Report of activities, 2001–2004, WHO/CDS/CSR/LYO/2004.17.

[151] World Health Organization, *Laboratory Biosafety Manual* (note 5)

[152] 'WHO declares itself satisfied with Russian lab safety procedures', Associated Press, 25 Oct. 2002.

[153] WHO, Department of Communicable Disease Surveillance and Response, Biosafety, Programme of work for the 2004–2005 biennium, 2004; and WHO, Department of Communicable Disease Surveillance and Response, Biosafety Project Proposals 2005, 2004.

questions dealing with bio-safety and bio-security. The WHO is developing guidelines for laboratory bio-security together with the FAO and the OIE.

The G7 + Health Security Initiative

At a meeting in Ottawa on 7 November 2001, health ministers from the G7 group of countries together with the Mexican Health Minister and a representative of the European Commission agreed to a concerted global action. This was aimed at strengthening public health preparedness and response to the threat of international nuclear, biological and chemical (NBC) terrorism. The Global Health Security Action Group was formed to implement agreed actions. The plan involves sharing of information and experiences on preparedness and response plans, collaboration between laboratories (including BSL4), the development of risk communication and management methods, the promotion of mutual assistance as means to counter attacks, and training for health staff. They also agreed to strengthen the virtual smallpox vaccine reserves of the WHO from the existing 600 000 to 200 million doses. An exercise in 2003 was held to evaluate smallpox plans and communications. The Global Mercury exercise under Canadian leadership involved eight countries and lasted for three days.[154] There is also a World Bank initiative to promote the fight against infectious diseases by concluding an agreement with Russia on tuberculosis and AIDS control projects, supported by a $150 million loan.[155]

The Cartagena Protocol on Biosafety under the Convention of Biological Diversity

Under the Convention on Biological Diversity, the Cartagena Protocol on Biosafety was adopted in Montreal on 29 January 2000. It provides a framework, based on the precautionary principle, for the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health and specifically focusing on trans-boundary movements. The United Nations Environment Programme/Global Environment Facility (UNEP/GEF) National Biosafety Frameworks programme aims to enable states to comply with the Cartagena Protocol with key elements consisting of legal instruments, administrative systems, risk assessment and management, and systems for public participation. The first step is to help states develop their own national bio-safety framework and then to help them implement it by focusing on bio-safety policy, regulations, system to handle requests, monitoring and inspection, and public information.[156] A bio-safety clearing house is being supported to promote the exchange of experience on issues of relevance to bio-safety. Much of the UNEP/GEF programmes are similar to those which are required for effective security and oversight of pathogenic micro-organisms and toxins.

[154] 'Canada leads bioterror test: Fictitious smallpox outbreak hits Vancover. Eight countries put their health officials through simulated crisis to assess reactions, communications', *The Gazette*, 9 Sep. 2003; and Commission of the European Communities, Communication from the Commission to the Council and the European Parliament on Cooperation in the European Union on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security), Brussels, 2 June 2003, Doc. COM(2003) 320 final.

[155] 'Russian Federation and World Bank concluded negotiations on tuberculosis and AIDS control project', Press release, 23 Dec. 2002.

[156] Further information is available at <http://www.unep.ch/biosafety>.

The OECD: biological research centres

The association of world culture collections, the World Federation for Culture Collections[157] (WFCC), and its US and EU organizations have urged its members to strictly follow all national and international legislation on the distribution of sensitive materials to third parties.[158] However, these organizations cannot monitor or enforce compliance, and the statements that have been issued are not enough to establish minimum bio-security standards.

The OECD countries have systems in place to address bio-safety, and the systems employed by many also indirectly address the question of bio-security.[159]

An example of an initiative to secure dangerous pathogens, the biological resource centres (BRC) programme, is being carried forward by the OECD (of which the EU is one member). The aim is to establish a global network of BRCs and to harmonize national standards and regulations to ensure the availability of rare biological resources and permit free exchange of microbial cultures. To certify and enforce the agreed standards on a national basis, the OECD Task Force will set up an accreditation system. Each participating government will select a certifying agency which will conduct periodic checks of bio-safety and bio-security at the participating BRCs. The BRC standards will probably be fairly modest and general, and will not be legally binding; but they are an essential part of the infrastructure underpinning life sciences and biotechnology.[160] BRCs consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. microorganisms and plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics.[161] The Convention on Biological Diversity has raised the importance of BRCs in the eyes of governments and the scientific community.

There is a need to support the development of an accreditation system for BRCs; facilitate international coordination among them; take them into account when establishing rules and regulations; develop policies to harmonize the operational parameters under which BRCs work; and support the establishment of a global BRC network.[162] A European network of BRCs exists in the Common Access to Biological Resources and Information (CABRI). In addition there is an international network linking biodiversity

[157] It includes 489 culture collections in 60 countries (see <http://wdcm.nig.ac.jp/wfcc/GuideFinal.html>) with the WFCC-MIRCEN World Data Centre for Microorganisms (WDCM).

[158] World Data Centre for Microorganisms, 'Culture collection organization statements on biological warfare', <http://www.wdcm.nig.ac.jp/announce.html>; Broad, William J., 'World's largest germ-bank union acts to keep terrorists from stealing deadly stocks', *New York Times,* 23 Oct. 2001, p. B9; and European Culture Collections Organization, 'Prevention of proliferation of dangerous microorganisms: The ECCO principles', <http://www.eccosite.org/prevention.htm> (accessed 25 Mar. 2003).

[159] OECD International Futures Programme (IFP), Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources, Frascati, Italy, 17–19 Sep. 2004, Chairman's summary.

[160] Scott Stern, *Biological Resource Centers: Knowledge Hubs for the Life Sciences* (Washington, DC: Brookings Institution Press, 2003); Organisation for Economic Co-operation and Development (OECD), *Biological Resource Centers: Underpinning the Future of Life Sciences and Biotechnology* (Paris: OECD, Mar. 2001); and Tucker, J., 'Biosecurity: Limiting terrorist access to deadly pathogens', United States Institute of Peace, *Peaceworks*, no. 52 (Nov. 2003).

[161] Definition based on the one adopted at the 1999 Tokyo Workshop on Biological Resource Centres, where the concept of BRCs as an outgrowth of conventional pre-genomics *ex situ* collections of biological materials was developed – and incorporating scientific developments since 1999.

[162] OECD, 'Biological resource centres, underpinning the future of life sciences and biotechnology', Paris, Mar. 2001, <http://www.oecd.org/dataoecd/55/48/2487422.pdf>.

databases to make them universally accessible via the Global Biodiversity Information Facility (GBIF), with 20 OECD and non-OECD countries participating initially.[163]

The Biological and Toxin Weapons Convention and bio-security

At the BTWC Experts Meeting in 2003, bio-safety/bio-security was on the agenda for discussion. Some states were not clear about the terminology or about how the two concepts differed. States noted the need for risk assessments as a tool for designing appropriate and balanced legislation. It was also noted that relying on self-regulation by facilities in the area of bio-security is likely to be an inadequate approach, and formal government-based oversight arrangements based on legislation would probably be necessary. Legislation aimed primarily at health and safety, bio-containment in public health or agriculture, or the protection of the environment may also contain provisions that provide directly or indirectly for the maintenance of security and oversight of pathogenic micro-organisms and toxins. Many states saw legislation that addresses facilities, personnel, equipment and transfers as a means to reduce the risks of proliferation and bio-terrorism. For a national bio-security programme the key points discussed included risk assessment, legislative oversight and enforcement, training and education, security concepts, bio-safety, personnel management, facility design, good science practice and other standards, ethics, and information strategy. Some states were more vulnerable to unauthorized access to facilities with dangerous pathogens as they lacked both appropriate legislation and security.[164] A number of states presented papers on their legislation and on bio-safety/bio-security.[165] The importance of strengthening national infectious disease surveillance to improve global surveillance and capabilities for responding rapidly to naturally occurring or deliberate diseases was pointed out.[166]

Export control regimes: the Australia Group

Export control involving licensing and oversight of specific trade will delay access to WMD-related technologies, goods and know-how, and thus delay WMD programme development. There is a need to enhance cooperation between states in regulating and monitoring trade in BW-related areas.

The Australia Group (AG) has helped to harmonize the export control systems of partners. Because of the enhanced threat of biological and chemical terrorism, there has been agreement in the AG on widening the export controls on CBW-related items. The lists of agents and equipment have been extended and controls on technology that can be used to produce equipment of CBW relevance have been introduced. The AG has also issued common guidelines for partner countries to use. There is also a 'catch-all clause', meaning that a non-listed item can be controlled if a state receives information that indicates that the item is aimed for CBW programmes or CBW terrorism activities.

In June 2002 the AG, responding to concerns about the acquisition of BW agents by terrorists, agreed that transfers of biological agents on the AG Export Control Lists

[163] OECD (note 162).

[164] Hersh, M., 'A view to the BWC 2006 Review Conference: A focus on risk', Draft, Presented at Meeting the Challenges of Bioterrorism: Assessing the Threat and Designing Biodefence Strategies, International Bioterrorism Conference in Furingen (Nidwalden), Switzerland, 22–23 Apr. 2005; and Final Report, Meeting of States Parties 2003, Chairman's Statement.

[165] See the BTWC web site, <http://www.opbw.org/>.

[166] 'Experts exchange ideas for strengthening national and international measures against infectious and deliberate diseases' (Biological Weapons Convention Experts meeting, 19–30 July 2004), UN News from Geneva, 2 Aug. 2004, <http://www.acronym.org.uk/docs/0407/doc09.htm>.

should require individual export licences. Problems are the kind of assurances that should be submitted by end-users for transfers or the need for post-shipment inspections of biological agents by the exporter. In the EU there is common Community regime for the control of exports of dual-use items and technology.[167] This regulation was updated in 2003 and 2004 to take account of AG recommendations. The AG has widened controls so as to also cover attempts by terrorists to acquire equipment and agents in the biological area, and the lists of agents have been expanded.[168]

UN Security Council Resolution 1540

UN Security Council Resolution 1540 of 28 April 2004 requires states to take steps to deny terrorists seeking WMD and their means of delivery, and punish them. States are requested to adopt and enforce 'appropriate, effective' laws and measures, such as export and border controls, to prevent non-state actors from acquiring and manufacturing WMD or related materials.[169] It is also mentioned that states should take cooperative action to prevent illicit trafficking. States should adopt national rules and regulations where this has not been done.[170] Governments should report in six months to a committee charged with reporting on its implementation to the UNSC. It is significant that the resolution was adopted under Article VII of the UN Charter, which recognizes punitive actions to preserve peace and security. It was also stated that none of the obligations set out in this resolution shall be interpreted in such a way as to conflict with or alter the rights and obligations in other arms control agreements.[171]

Proposals for international regime/standards for bio-security

It has been proposed that international bio-security standards, or a protocol that would prevent proliferators and terrorists from acquiring BW agents and know-how, as well as making the tracing of agents used in bio-terrorism attacks easier, should be developed. This could include legal commitments, a set of universal standards, and an oversight mechanism. It could further include emergency response plans in case of bio-security breaches, a mechanism for accounting and controlling pathogens and toxins in storage, use or transfer, the registration or licensing of facilities and/or personnel working with dangerous pathogens, and physical security measures.[172]

Work is said to be in progress on a code to establish a global network on bio-security.[173]

[167] Council of the European Union, Council Regulation (EC) amending and updating Regulation (EC) no. 1334/2000 setting up a Community regime for the control of exports of dual-use items and technology, Brussels, 7 July 2004, Doc. 11121/04, as amended.

[168] 'Australia Group concludes new chem.-bio control measures', *Arms Control Today*, July/Aug. 2002, p. 21.

[169] United Nations Security Council Resolution 1540, 28 Apr. 2004.

[170] 'UN Security Council unanimously passes resolution on WMD, measures designed to punish those who sell WMD components, technology', US State Department, News from the *Washington File*, 28 Apr. 2004; and 'UN adopts resolution to keep weapons of mass destruction from terrorists', Associated Press, 28 Apr. 2004.

[171] 'Security Council unanimously adopts resolution on denying terrorists WMD', *Arms Control Today*, May 2004, p. 34.

[172] Tucker (note 160); Tucker, J., 'A strategy for international harmonization of biosecurity standards under SCR 1540', Paper presented at the Workshop on UN Security Council Resolution 1540 as it Pertains to Biological Weapons, Palais des Nations, Geneva, 3 Dec. 2004; and Tucker, J. B., 'Preventing terrorist access to dangerous pathogens: The need for international biosecurity standards', *Disarmament Diplomacy*, no. 66 (Sep. 2002), <http://www.acronym.org.uk/dd/dd66/66op2.htm>.

[173] Daoust-Maleval, I., 'A tool for biosecurity', Inter Parliament Conference organized by the European Commission's Non-proliferation and Disarmament Co-operation Initiative (NDCI), Strengthening the Global Partnership, International Consortium Meeting. Strasbourg, 20–21 Nov. 2003, <http://www.sgpproject.org/events/2003_Nov_Strasbourg.html>.

Negotiating global bio-security standards would reduce the threats while reinforcing the legal prohibitions in line with the BTWC. The need to include in such a regime measures for transparency of national bio-defence programmes and technology transfer to developing countries in order to enhance their level of bio-safety and bio-security has also been pointed out. This regime should be taken forward within the framework of the BTWC and with the active participation of the scientific and public health (WHO, FAO and OIE) communities.[174]

Another example is making biological or toxin terrorism an international crime, which would clearly establish a powerful norm, facilitate detection and interdiction, and promote international cooperation. International criminalization would enable international law enforcement agencies like Interpol and the World Customs Organization or UN organs to be more active.[175] It would create international law obligations not only to adopt criminal laws but also to vigorously enforce them.[176] There is a draft that is based on seven model treaties that establish universal jurisdiction. The four strategies were:[177]

- to criminalize the hostile use of biological agents by defining prohibited conduct and requiring states to establish criminal jurisdiction and to cooperate against such conduct;
- to require that states establish a licensing system for legitimate biological activities that involve specifically designated (listed) dangerous pathogens;
- to establish an international mechanism to promulgate bio-safety and bio-security standards for listed pathogens; and
- to strengthen international information-gathering and analysis capabilities in order to identify and investigate and thereby thwart illegal activity.

Consultations have now been held within the European Community, and the Netherlands has introduced the draft convention in the EU Council's Public International Law Committee for review in national capitals. There have been contacts with the International Criminal Court. It is possible that the draft has now left the area of academia and is being processed by governments.

Non-governmental bodies' activities in support of bio-safety/bio-security

The International Centre for Genetic Engineering and Biotechnology (ICGEB) has a Global Biosafety initiative[178] which includes information, database, capacity building, training and workshops, international cooperation, and participation in the Interagency Network for Biosafety (IANB) and the Convention on Biodiversity/SBSTTA/Biosafety clearing house. There is also a new initiative to promote self-regulation of the biotechnology industry: the International Council for the Life Sciences (ICLS) will be an action-oriented forum where members will discuss responsible, ethical and sound

[174] Atlas, R. and Reppy, Judith M., 'Globalizing biosecurity', *Biosecurity and Bioterrorism: Biodefense Strategy, Practice and Science*, vol. 3, no. 3 (2005), pp. 51–60.

[175] Kellman, B., 'Criminalization and control of WMD proliferation: The Security Council acts & template of national measures to prevent bio-crimes', Paper presented at a Workshop on Security Council Resolution 1540 and Biological Weapons, Geneva, 3 Dec. 2004.

[176] Gilman, T. K., 'Search sentence, and (don't) sell: Combating the threat of biological weapons through inspections, criminalization, and restrictions on equipment', *Journal of Transnational Law and Policy*, vol. 12/2 (2003), pp. 217–53.

[177] 'Draft Model Convention on the Prohibition and Prevention of Biological Terrorism', *Terrorism and Political Violence* (London), vol. 14, no. 4, pp. 163–208.

[178] Further information is available at <http://icgeb.org/biosafety>.

business and scientific practices as well as bio-safety, bio-security and other key issues. The ICLS was launched on 15 April 2005.[179] It is to contribute to enhanced international standards of public safety and security on a global scale through responsible, ethical, and sound business and scientific practices. Industry wants to become more engaged on these issues and does not want to be seen as part of the problem.[180]

There are several non-governmental bodies in the USA that take active part in or monitor threat reduction activities, such as the Nuclear Threat Initiative (NTI), the Center for Nonproliferation Studies at the Monterey Institute for International Studies, the Center for Strategic and International Studies (CSIS) and Russian–American Nuclear Security Advisory Council (RANSAC). Others deal with the topic of threat reduction on an ad hoc basis, but it can be noted that there are very few in Europe except for the Landau Network – Centro Volta, the Stockholm International Peace Research Institute (SIPRI) and the Geneva Centre for Security Policy.

[179] Chemical and Biological Arms Control Institute (CBACI), 'The future of the life sciences: Reaping the rewards and managing the risks', <http://www.cbaci.org/ nonp/projects.html>; and Charter, International Council for the Life Sciences, Draft 9, 25 Feb. 2005.

[180] Chemical and Biological Arms Control Institute (CBACI) and International Institute for Strategic Studies – US (IISS – US), 'The future of the biotechnology industry: Safeguarding the opportunities and managing the risks', Project overview, 22 Oct. 2003.

4. Pros and cons of the main bio-security building approaches

Enhancing physical security

The enhancement of physical security at facilities with dangerous pathogens and toxins is essential, and the level of security has to be based on a risk assessment in each case. The level of awareness concerning the risks from outside intrusions is usually low in many places, so that information and awareness raising will be required. The risk of causing mistrust and suspicions among the local community about the activities at a site makes it essential not to increase security measures more than needed. This in turn will depend on the acceptance of local and national authorities, and on locals being able to trust the information given. In many former Soviet states this is still a problem, and help with information and communication strategies to the general public will be important.

Development guidelines for how to keep an open and transparent attitude to the R&D carried out at facilities should be part of a bio-security strategy. There is also a need to keep a national register of all facilities, governmental or not, which keep or work with dangerous pathogens, indicating their levels of bio-safety and bio-security. Enhancing security measures within a facility would not meet this kind of problem but the personnel must be convinced that the measures taken really are needed and are based on a common view of the risks involved. If the security measures become too stringent and cumbersome this might negatively impact on scientists' willingness to carry on research on some dangerous pathogens.

It is not possible to set uniform rules for all facilities doing work with dangerous pathogens or toxins as the need for more detailed and elaborate rules will also depend on the experience of the personnel in a facility and the security culture among them. In many places it would be beneficial to concentrate culture collections and work with dangerous pathogens to a few central laboratories for which adequate bio-security can be provided. This is also why there is a need for a national strategy on how work with dangerous pathogens should be handled. This has been done, for example in the Central Asian republics, but it could be needed in Western countries as well.

Developing standards

International standards such as the WHO bio-safety manual are recommendations, and it is up to every state and facility how it acts on them. When standards are prepared the process of developing them is most important as it will engage a very broad international community of experts that will initiate national discussions and reviews of the standards under discussion. To achieve broad recognition standards should be developed by well-established organizations of high international reputation, like the WHO. Over time these standards become the norm, as the WHO bio-safety levels have done, and become integrated in national regulations and legislation.

Codes of conduct for scientists are just that—codes and something to follow for the individual, like ethics or the recommended way of performing science. On the other hand there are codes of practice which can be seen as implementing legislation or regulation and are agreed by organizations, companies and so on. In this case the rules have to be followed, for example, GMP if a pharmaceutical company wants to sell pharmaceutical products in a specific market. How these kinds of standard or regula-

tions are implemented and whether there is an oversight mechanism are crucial questions. The general culture will also influence whether voluntary, self-regulating standards are sufficient or whether stricter regulations or legislation will be required.

It is not only the pathogens but perhaps even more the essential know-how that must be kept from misuse, and to prevent threat from insiders this has to be the major focus for preventive measures. For this a culture of bio-safety and bio-security has to be promoted at all levels in institutes, as well as carrying out personnel checks.

Bio-security standards could be of several types, such as WHO standards, or codes of practice agreed upon by laboratories working with dangerous pathogens or toxins; or they could take the form of legislation and regulation. How this will be handled and which mix of measures is adopted will depend partly on the local situation and administrative culture. It is, however, important that each state initiates a process to develop bio-security standards and legislation as appropriate bearing in mind the necessary balance between security needs and not hindering essential legitimate research.

Encouraging the development of internationally accepted bio-safety and security practices at Russian institutes will be essential in promoting Western investment, and the creation of a safety culture in Russia will have multiple benefits.[181] Questions that should be part of these elaborations in general include (a) whether licensing/registration of facilities and/or scientists working with specific dangerous pathogens or toxins is required, and (b) whether there is a need for an oversight mechanism for special types of research, and what mechanisms would be required if this is so. It is also important that codes, regulations or legislation do not conflict with international treaty obligations.

International control

Bio-security standards and measures should be developed in close cooperation with international partners so that they are harmonized at the international level and will not create trade barriers or hinder the exchange of research and so on. An example of this is the guidelines the UN has developed for the transport of dangerous goods, including pathogens, which are in many cases incorporated into national regulations. Another area where some kind of international oversight is needed is culture collections with dangerous pathogens and toxins, and here the WFCC and OECD BRC can play a role.

Because so many actors and initiatives involved it is essential to improve coordination between those currently working on bio-security issues. One forum where this should be done is the framework of the BTWC, supported by the WHO, the FAO and the OIE. Strengthening the BTWC is a critical part of achieving enhanced global bio-security. As there yet is no international mechanism (like the OPCW for the CWC) for monitoring implementation of the BTWC. Other mechanisms for oversight have to be devised.

Concerning bio-safety there is no international control. It is up to each state to develop its own system for protecting personnel working with dangerous pathogens or toxins. When it comes to security issues this will even more be an issue for governments and be more of an international concern. It has been proposed that negotiations should be initiated on international bio-security standards or a protocol. This would be essential to establish agreed guidelines including how risk group classification should be carried out. Initiating such a process would also generate awareness of the issues involved and result in national initiatives. In Russia a process has been initiated to develop a programme for improving chemical and biological security.

[181] Della Ratta, R., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay Brussels, 25 Jan. 2005, pp. 57–60.

5. The obstacles to biological security building

A major concern is that threat reduction programmes have so far not been able to initiate a dialogue, let alone reach the military microbiological facilities subordinated to the Russian Ministry of Defence with support proposals. Its scientists are still prevented from making international contacts or engaging cooperation. Even if progress is slowly being made on the issues of access and transparency, much more could be expected from the Russian Government's side. The previous unsupportive attitude to threat reduction activities in the biological area must change and result in increased openness. The problem of US access being denied, not only to the biological facilities under the Russian Ministry of Defence but also to those under Ministry of Health, has damaged US–Russian relations in this area for a long time. It can always be discussed that the access could be reciprocal, but perhaps confidence can be achieved through other means and at least exchange of information and contacts should be promoted. This situation has to be resolved through diplomatic means in order for progress to be made.[182] Senator Richard Lugar has tried himself to achieve access to one site, Kirov 200, which had been transferred from the MOD, but without success.[183]

There are also problems with access to other institutes, like the anti-plague institutes under the Ministry of Health and Social Development, and there has been no reason why they should not participate in support programmes as in many cases they work with very dangerous diseases. Nor is the situation concerning bio-safety/bio-security measures at these institutes known. If the situation is similar to those at institutes in Central Asia a good deal of international support will be needed.

This is in contrast with the situation in the former Soviet republics, where there have been no problems with achieving agreements with governments for threat reduction programmes, with discussing the national priorities for the institutes involved, or with access to or cooperation with specific institutes. If access can not be permitted to specific facilities or parts of facilities there could be other means of achieving transparency if the political will is there. There is an urgent need to solve the issues connected to access so as to achieve a more positive and non-confrontational atmosphere between the USA and Russia in the biological area. The EU is perhaps better placed to handle this problem and also achieve results, and this should therefore be one priority.

One model that could be copied for achieving transparency of national bio-defence programmes is the one used by the Canadian Government. Canada has mandated a committee to review the CBW defence programme annually to ensure that activities are defensive in nature and re conducted in a professional manner with no threat to public safety or the environment. Annual reports are published and available on the Internet.[184]

The previous Soviet culture of limiting information and openness for secrecy and national security reasons must be changed. Over time this is gradually changing for the better, and in the Russian scientific community it has already taken place through increased international contact, access to the Internet, and opportunities to read and publish in international journals. There is, however, also a culture of individuals not being used to making decisions themselves but relying on their superiors for this and

[182] Averre, D., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay Brussels, 25 Jan. 2005, pp. 51–56.

[183] Kobyakov and Orlov (note 115).

[184] United Nations, 'Canada's biological and chemical defence review committee: Transparency model, Meeting of Experts, Geneva 18–29 August 2003', BWC/MSP.2003/MX/WP.28, 18 Aug. 2003.

not questioning decisions taken. It is essential to support work on codes of conduct for scientists and others.

Where bio-security is concerned, one obstacle is that personnel working in laboratories in general are not used to thinking in security terms and in many cases believe that the bio-terrorism risks are hyped, and thus that security problems are not so serious. To overcome this awareness-raising activities on a worldwide scale are of the utmost importance. In the FSU there is also a lack of trust in the authorities and their rules and regulations. Because of this participation in the international discussions on the issues of bio-security will help the national authorities to achieve positive results.

There is no problem with the knowledge base concerning dangerous pathogens or toxins, or understanding of bio-safety. The level of bio-safety in laboratories in Russia is in many cases lower than that in Western laboratories, partly because of the lack of sophisticated protective equipment for financial or other reasons. Much work is probably still needed, but information on the current situation in Russia is lacking as no surveys have been carried out. There would be a need for bio-safety upgrades as well as training of personnel.

Concerning bio-security, national surveys are needed as are technology, awareness raising, and training to achieve improvements. One major challenge if bio-security is to be improved is preventing the transfer of know-how that can be misused. Transfers can take place in many ways and by various means. Such intangible technology transfers will be extremely difficult to handle and control. Much work will be needed in this area in most countries, and there are no ready solutions to hand in Western countries, as bio-security issues are still under discussion and not well developed.

Political fluctuations will also influence progress and the atmosphere of cooperation. States' social and economic development needs to be supported if the aims of non-proliferation prevention support are to be achieved. There is no risk of major change in Russia in the near future that would negatively affect current threat reduction activities.

Funding is and has been a problem for the biological area: for political and other reasons the nuclear and chemical areas have been given higher priority. This has to change, not least because of the enhanced risks of bio-terrorism and the still urgent need for support in Russia, the NIS and worldwide. One obstacle has been how to verify that funds are being used for the purposes they were intended for and that no diversion is occurring. The science centres have devised mechanisms to handle this, and the USA has used certification that no BW activity is carried out at institutes being funded. For sensitive areas of research the USA has also placed scientists on-site in Russian laboratories, although only for special situations. It is clear that a small part of the funds for a project is often diverted in order to get a project approved, but there is no information on how common this is or on the amounts involved. Financial auditing and follow-up is carried out by the science centres, usually to the funders' satisfaction.

To achieve lasting results in redirecting scientists or self-sustainable commercialization, a long-term approach has been found to be needed; and longer-term projects are needed for research as well so that scientists can see a future in a new research area. At the same time careful review is needed of which research groups and areas of research that have reached international standards should be priorities for support. Further downsizing of the very large number of scientists and institutes. is probably still needed. Here a dialogue with governments on priorities for funding from a scientific point of view is needed. Much has been achieved at facilities in ensuring physical protection, providing training and raising standards to the internationally recognized GLP and GMP levels, but many others require sustained investment in terms of both financial and administrative resources from international organizations.

Concerning bio-security very little has been achieved so far. It is important that the support given is not a one-off investment but is followed by actions for maintaining equipment, investments or training. The focus for the CTR programmes has been on building infrastructure and capacities at former Soviet facilities in order to allow them to become self-sustaining commercial enterprises. There are and have been many hurdles to doing this—lack of access to sensitive facilities; inadequate government support; poor infrastructure and communications; lack of experience of putting together and managing market-oriented business plans; inability to focus on demand pull models; regulatory issues; and meeting international GMP/GLP standards.[185]

The fight against bio-terrorism will need the active cooperation of Russia and the NIS with their vast knowledge base concerning dangerous pathogens and toxins. Measures are needed to achieve a real and lasting partnership for our own security. From a global perspective the relatively small sums of funding needed to improve bio-security in order to reduce the availability of pathogens and know-how are well spent.

Threat reduction or non-proliferation prevention activities can be seen as a unique non-proliferation tool that differs from and is complementary to arms control and non-proliferation treaties. Their advantage is that a step-by-step approach can be used, from confidence building to destroying weapons, in order to achieve the goals set. This can be seen in the mix of measures and projects in the US threat reduction activities. The difficulty is rather how to evaluate if they have been successful or not from a non-proliferation point of view. The international non-proliferation commitments such as the BTWC set a norm but as long as there is no control or verification mechanism it has not and probably will not be sufficient to prevent covert BW activities. Other commitments like the Global Partnership involve declarations but no joint actions in the biological area. Other initiatives, like UN Security Council Resolution 1540, will strengthen and promote implementation of the BTWC and national legislation but it is too early to say what preventive effect it will have on potential terrorists who are determined to acquire BW agents. The AG export controls have had a preventive effect but have clear limitations because of the difficulties of detecting illicit transfers of pathogens.

The EU is in a unique position to handle several of the problems the USA has faced in its biological threat reduction activities. It is now clearer in which areas problems have surfaced, and there is a better understanding of the reasons for some of them, which makes it easier to propose possible ways forward. The EU has very good relations in general with Russia, and can use a broad range of instruments such as trade, research, public health, agriculture and industrial relationships to promote non-proliferation aims. One example is the direct contacts the EU (in contrast to the USA) could take, without problems, with the Russian Ministry of Health and Social Development to achieve cooperation on smallpox diagnostics.

The EU has many instruments at its disposal. The difficulty lies in the EU's structures, between the European Commission and the Council. The question of how to achieve a better coordination mechanism in the EU is outside the scope of this study, but one is urgently needed, to set the goals for threat reduction programmes and be able to evaluate ongoing activities, if the EU is to get more positive spin-offs from its financial support and achieve better results in some of the problematic areas than the USA. So far the EU's engagement has been through the science centres, and only then in a passive manner by agreeing to projects presented to the centres but not actively searching for projects, in contrast to the US way of operating.

[185] Averre, Luongo and Martellini (note 64).

6. Conclusion and options for European security-building efforts

The global problem of infectious diseases

The continuing appearance of highly virulent emerging and re-emerging communicable diseases highlights the need for coordinated preparedness in support of global public health. A disease outbreak in one country can be spread internationally in a matter of hours or days. Outbreaks of infectious diseases continue to have significant consequences for public health, agriculture and the global economy.[186] Many experts believe that the risk of a new flu pandemic killing millions is real.[187] The consequences of an outbreak of infectious disease resulting from deliberate use of a pathogenic micro-organism could be at least as damaging as naturally occurring infections, and possibly more so. The anthrax letters in the USA in 2001 had a relatively modest health impact, with five fatalities and 22 persons injured, but they resulted in enormous social disruption and economic damage.

Timely and detailed surveillance for infectious disease outbreaks or epidemics is essential for most states' security. This is particularly so for diseases which may have major impacts on health and international trade, and for the ability to detect and recognize the possible deliberate release of an infectious agent. Most crucial is the ability to detect novel or unusual diseases quickly and specifically so that surveillance is a real-time process. People, knowledge and products increasingly move across borders, information is becoming easier to get hold of through the Internet, and more widespread expertise has made it easier to acquire dangerous pathogens (BW agents), materials or know-how.

Measures to reduce global biological risks due to accidental and deliberate outbreaks of infectious disease require a coordinated, global strategy. Many disease control strategies focus on response to an outbreak, such as increasing the effectiveness and availability of therapeutics, improving diagnostic capabilities, and developing preparedness and response plans. In contrast, preventive strategies provide an opportunity to counter risks before they result in infection—an example being efforts to improve bio-security and bio-safety.

The report of the UN High Level Panel mentions that the security of the most affluent state can be held hostage to the ability of the poorest to contain an emerging disease. Every threat to international security today enlarges the risk of other threats. Improving global disease-monitoring capabilities can be seen as a means of fighting new emerging infectious diseases, defending against the threat of biological terrorism and building effective, responsible states. That a high-damage biological attack has not occurred is not a cause for complacency but a call for urgent prevention. The report further states that States Parties to the BTWC should without delay return to negotiations for a credible verification protocol, and should also negotiate a new bio-security protocol to class-

[186] The outbreak of foot and mouth disease in the UK in 2001 caused economic losses of about €11 billion. The outbreak of SARS in 2003 infected over 8000 people, killed almost 800 and had considerable impact on economies in the Pacific Rim and Canada. Outbreaks of avian influenza in 2004 inflicted losses in Asia estimated to be €400 million, WHO, Department of Communicable Disease Surveillance and Response, Laboratory Biosecurity WHO Guidance, WHO/CDS/CSR/LYO/draft9, 2004.

[187] The 'Spanish flu' 1918–19 pandemic killed at least 20 million, possibly 100 million people. Enserink, M., Looking the pandemic in the eye, *Science*, vol. 306 (15 Oct. 2004), pp. 392–94; and 'WHO warns of bird flu pandemic', 23 Feb. 2005, <http://news.bbc.co.uk/go/fr/-/1/hi/world/asia-pacific/4289637.stm>.

ify dangerous biological agents and establish binding international standards for the export of such agents. It calls attention to the overall deterioration of the global health system, which is ill-equipped to protect us against existing and emerging infectious diseases, and it highlights both the promise and the perils of advances in bio-technology.[188] There is a basic dilemma in finding the right balance between health needs and security needs so that scarce resources can be used in an efficient way and be maximized.

There is a need for the EU to integrate health issues more systematically into its security strategy. In addition, better coordination is needed between different functions in the European Commission and between it and the Member States. One obvious area is to increase support and enhance the epidemiological surveillance networks, bio-safety and bio-security elements, diagnostic capabilities, drugs and vaccine development, training and preparedness planning of developing countries. This is common wisdom but financial support from the international community is still limited, and this has to change. Here the EU could play a more prominent role by *strengthening its cooperation with the WHO, the FAO and the OIE using the ECDC as a competent actor*. It can be mentioned that cooperation is already ongoing in many areas, for example, on epidemiological surveillance in the Mediterranean and North African countries.

Concerning the number of laboratories, institutes or commercial enterprises that might have collections of dangerous pathogens or toxins, there is no information except concerning commercial culture collections, of which there are around 150. There has been no comprehensive review of the situation worldwide. It has been estimated that *c*. 30 per cent of these pose a security risk. There has also been no review made of the global situation concerning bio-safety or bio-security levels at laboratories working with dangerous pathogens or toxins. There is a need to collect information from states on the national situation and on this basis to be able to assess the global situation and the need for bio-security/bio-safety upgrades on a global scale.

In the EU there has not as yet been any action concerning bio-security within the EU, and there is no common definition among Member States of what the term would or would not include. Concerning culture collections it is clear from EU directives that states should have national registers of pathogens. However, there is no mechanism for monitoring whether Member States have implemented this or not, as no surveys have been carried out.

In most highly developed industrialized countries much has been done concerning bio-safety, and bio-security is being extensively discussed, but for most developing countries the recommended bio-safety standards will not be achieved for a long time and questions concerning bio-security are still not even being considered. On the other hand in developing countries the number of laboratories working with dangerous pathogens or toxins is probably limited compared to the numbers in Western countries.

The lack of information means that recommendations at this stage can only be of a general nature. It is also important to remember that it is not only a question of which agent, but also of whether it has been developed and prepared for weapons use. The virulence, antibiotic resistance and environmental stability of agents can vary, and in states with a previous BW programme there will still be agents kept that have specific characteristics that would be of special interest to potential terrorists or to states' programmes. Furthermore, there may still be scientists with special know-how of the process of weaponizing agents, which means that from a non-proliferation point of

[188] UN Secretary-General's foreword in 'A more secure world: Our shared responsibility. Report of the Secretary-General's High-level Panel on Threats, Challenges and Change, 2004'; UN document A/59/565, Dec. 2004.

view, when it comes to the risk of terrorists getting hold of agents, *the priority focus should still be on states that have previously had a offensive BW programme. In addition, geographical areas where terrorist groups are active or recruiting should be of specific concern*.

A few international organizations, including the WHO, the WFCC, the OECD, the EU, the G8 Global Partnership and the G7+ health ministers, have launched various initiatives in the bio-security field but they need better coordination. In addition, trade in microbial cultures, both within and between countries, is poorly regulated. Too stringent security measures will be viewed in many states as establishing trade barriers to protect the own market. It has been proposed that global bio-security standards should be negotiated within the framework of the BTWC.[189] As Potter has pointed out, 'there has been a tendency to focus only on the threat reduction aspect and not place enough emphasis on the relationship between disease surveillance, epidemiological response and bioterrorism preparedness', and 'not to utilize non-proliferation education and training as powerful tools to combat the spread and use of biological weapons'.[190]

The problem of proliferation of BW technology and know-how

In March 2003, the US General Accounting Office (GAO) review of US efforts to improve security in Russia concluded that after more than four years of effort the DOD had made little progress in addressing security concerns at the 49 biological sites, many of them former BW sites, where Russia and the United States have collaborative programmes.[191] These efforts have enhanced security against external threats but so far not improved security to address insider threats. The DOD still has only limited information on the location and security of sites that house collection of dangerous biological pathogens in Russia and it is thus still uncertain which sites should receive security improvements.

Despite years of US support, the Russian Government still keeps many biological sites closed to US security assistance programmes. The biological security programme has thus taken longer and accomplished less than expected. One reason given was the limited Russian cooperation. The GAO also recommended that the DOD should clearly articulate criteria to identify which biological sites pose the greatest security risks. Since this report some changes have occurred, but the general conclusions still hold.

It can, however, be concluded that *CTR and related programmes have helped prevent the loss of BW scientists to states of concern* and have provided the United States with details of previous BW-related research in Ukraine, Kazakhstan and Uzbekistan, as well as Russia's Biopreparat programme. But other key Russian facilities under the defence and health ministries have remained closed to outsiders. Objectives for assistance programmes should be to pre-empt BW proliferation at its source and prevent unauthorized actors access to BW capabilities. In this respect UN Resolution 1540 can make a positive impact depending on how it is implemented and followed up.

[189] Tucker, J., 'Biosecurity: Limiting terrorist access to deadly pathogens', United States Institute of Peace, *Peaceworks*, 2003; Tucker, J., 'A strategy for international harmonization of biosecurity standards under SCR 1540' (note 170); and Atlas and Reppy (note 174).

[190] Potter, W., Statement at the International Conference G8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, Moscow, 23 Apr. 2004, <http://www.pircenter.org/rus/club/steno.html>.

[191] US General Accounting Office (GAO), 'Weapons of mass destruction: Additional cooperation needed to facilitate US efforts to improve security at Russian sites', GAO Report 03-482, Mar. 2003.

Very few studies have focused on evaluating the threat reduction and non-proliferation initiatives connected with former BW programmes and facilities.[192] There is a lack of detailed studies that have examined the types of biological project that have been funded, the types of research and the outcomes from the research funded, and compared it with the research proposals.

One recommendation has been the establishment of a parallel G8 effort to broaden the coverage of current BW threat reduction efforts. The main elements in a counter-proliferation strategy in the biological area are to eliminate any remaining BW-sensitive materials or to make them secure, and to prevent scientists and technicians who were previously employed in BW programmes from using their skills to assist proliferating states or terrorist groups. The main source of such materials, agents specifically developed for weapons use (having specific characteristics) and dissemination methods or weapons is still the FSU. There are also some other initiatives to promote new activities in the biological threat reduction area.[193]

The generally accepted assessment of this foreign support is that the threat reduction and non-proliferation efforts have succeeded to a large degree. The fears expressed at the beginning of the 1990s that Russian BW scientists and technicians would emigrate in large numbers have not materialized, although rumours maintain that a few scientists have sold their services to states of concern. Generally, however, former Russian WMD scientists have been unwilling to leave Russia for long periods. The internal brain drain has been much larger than the external. Nearly all those who left Russia for a shorter or longer period went to the USA or other Western countries where the laboratories are well-equipped and financial resources available.[194] The Russian Government recently identified biotechnology as a target industry for the 21st century. This could provide a commercial platform for former BW facilities that could help to address the critical gaps in health care and support the development of innovative medical techniques.

An improved mechanism for coordination between donors and a clear strategy on how to achieve the proliferation objectives are needed from Western partners so that cooperation is well focused on the areas of technology or institutes of most concern. Priority should be given to facilities that are known to be or which a recipient country declares as having been part of a previous BW programme as they might still have agents of weapons grade, special sensitive equipment, and know-how of a sensitive nature. Special concern should be given to institutes which have so far not participated in CTR programmes.

In many cases political constraints will severely limit how far non-proliferation support programmes can go and what they can achieve. A state's willingness to cooperate

[192] Those that have focused on evaluating the threat reduction and non-proliferation initiatives include: Roffey, R., 'Need for enhanced support for threat reduction in the biological area for redirecting production facilities', Paper presented at the Non-proliferation and Disarmament Cooperation Initiative (NDCI) Conference, London, 4–5 Mar. 2004; Roffey *et al.* (note 38); Averre, D., 'From Co-option to cooperation: Reducing the threat of biological agents and weapons', chapter 2 in Volume 2, *The challenges: Protecting Against the Spread of Nuclear, Biological and Chemical Weapons. An Action Agenda for the Global Partnership*, CSIS Report, Jan. 2003, <http://www.csis.org/pubs/2003_protecting.htm>; Averre (note 182); Ouagrham, S. B. and Vogel, K. M., 'Conversion at Stepnogorsk: What the future holds for former bioweapons facilities', Cornell University Peace Studies Programme, Occasional Papers 28, Feb. 2003; Höhl, K., Muller, H., and Schaper, A., edited by Burkhard Schmitt, *EU Cooperative Threat Reduction Activities in Russia*, Chaillot Paper no. 61 (European Union Institute for Security Studies: Paris, June 2003; Della Ratta (note 181); and Einhorn, R. J. and Flournoy, M. A., *Agenda for Action, Volume 1, Protecting Against the Spread of Nuclear, Biological and Chemical Weapons, An Action Agenda for the Global Partnership*, CSIS Report, Jan. 2003, <http://www.csis.org/pubs/2003_protecting.htm>.

[193] Phillips, K., Presentation at Next Generation Threat Reduction, Bioterrorism's Challenges and Solutions, New Defence Agenda, Bibliothèque Solvay Brussels, 25 Jan. 2005; and 'Russian official: US can't prove allegation', *Stuart News*, 16 Jan. 1999.

[194] Roffey, R., 'Need for enhanced support . . . ' (note 192).

will depend on a calculation of potential risks to its national security and other considerations—compare, for example, the Iraqi situation.[195]

In each case a balance has to be struck between the benefits of initiating and maintaining a dialogue on threat reduction and the risk that assistance in various forms could possibly be misused. An underlying issue is whether countries that pose particular risks would be prepared to provide adequate cooperation to achieve the aims set up for support programmes. There are technical constraints on support because of the need to have accurate information from the recipient country and to be able to verify it and ensure that assistance does not aid a covert BW capability that is being maintained in secret. This is extremely difficult if the recipient country is not open and transparent concerning previous activities.

There is a need to expand traditional threat reduction activities,[196] or rather proliferation prevention activities, much wider on a global scale. This should take into account that many aspects of strengthening countries' general preparedness, disease surveillance capabilities, diagnostic capabilities and levels of bio-safety and bio-security on a national, regional, local or facility base go hand in hand with reducing the risks that bio-terrorists can acquire agents, materials or know-how that could be misused in the biological area. It can then be discussed how the non-proliferation support should be distributed worldwide.

It has been noted that *many dangerous pathogens and culture collections worldwide have not been documented or secured. This should be undertaken as a function of proliferation prevention*, perhaps in collaboration with the WHO, the FAO and the OIE. On an informal basis, representatives of the WHO have a fairly good picture of where work is done on specific pathogens worldwide, but the information is scattered among many individuals and there is no complete picture.

There needs to be a *set of criteria to be used when deciding type of activities and/or geographical areas that are of priority for proliferation prevention activities*. In order to channel funding to the areas of greatest proliferation concern a graded approach could be used, for example, divided into four levels.

The highest priority should be given to states which have had advanced and large BW programmes in the past, especially if openness and transparency about those activities are limited, as the type of agents present will be more sophisticated and of more interest for large-scale dissemination. The number of facilities, the R&D performed and knowledge base of agents, the huge variety of dangerous pathogens with specific characteristics and knowledge of the more applied parts in a weapon programme all means that focus should still be on such states. These states and their assets will be the focus of terrorist groups that are aiming to cause mass-casualty incidents.

The next level would involve states that have recently had BW programmes or been part of such but where the government is transparent about previous activities and supportive in restructuring work in the biological area, and where facilities are supporting this kind of cooperative programme. Priority should be given to those where the level of bio-safety and bio-security is low.

The third level would be states where levels of bio-safety and bio-security are low but which still work with or possess collections with dangerous pathogens. Priority should here be given to unstable or terrorist-sponsoring states, or states in which terrorist groups are known to be active.

[195] Squassoni, S., 'Globalizing cooperative threat reduction: A survey of options', CRS Report to Congress, 15 Apr. 2004.
[196] Squassoni (note 195).

The fourth level would be states that request support, and which work with or possess dangerous pathogens, where the level of bio-safety and bio-security is low, the epidemiological surveillance systems are inadequate and terrorism activities are a concern.

To indicate the priority given to the different categories, it is proposed that 50 per cent of funding go to the first category, 25 per cent to the second category and 25 per cent to the third and fourth categories.

Biological threat reduction activities in Russia have not been the prime priority compared to other areas, as can be seen from the level of funding by donor countries so far for CTR programmes. This also means that *Russia still should be the main focus for non-proliferation prevention support* because of the size of its legacy, with many institutes and scientists that were involved or connected to the previous sophisticated BW programme. There are still priority facilities and scientists that have not been involved in this kind of non-proliferation prevention activity. The transformation from a passive support recipient to an active partnership means that Russia also should have a greater role in the planning and execution of this kind of support activities and be convinced that the biological area is of concern and a priority. Here a change is needed, and the Russian Government must become more supportive. This means, that similar to the way in which threat reduction programmes are carried out in the Central Asian republics, the actions taken and plans for improvements at institutes must be part of a government plan for upgrading bio-safety/bio-security as well as decisions as to the type of R&D to be supported. A new proliferation prevention partnership can develop and provide new opportunities for all those involved, including for the EU.

Strategies are needed for limiting and achieving the restructuring and conversion of any remaining BW infrastructure from the former programme so that activities can be sustained even after assistance programmes are reduced and eventually terminated.

Russia's and the NIS's former biological infrastructure remains a prime target for those interested in illicitly acquiring weapons, material or know-how. It is also clear that *proliferation prevention programmes should be extended beyond Russia and into other nations of concern*. Two such countries that should be priorities now are Belarus and Ukraine; then come other states in Central Asia and the Caucasus that have not yet received CTR-type support, not forgetting the Middle East and North Africa and parts of Asia. This type of proliferation prevention programme could also form part in establishing a WMD-free zone in the Gulf or Middle East.[197]

States should actively engage in the work of international organizations such as the WHO, the FAO and the OIE or the OECD to promote bio-safety and develop bio-security practices as this will help to achieve standards that can over time become generally accepted worldwide. The EU should here take on a more prominent role for setting standards outside Europe as well. There is also a need for an initiative on non-proliferation education and training.[198]

Proposed EU policy for non-proliferation programmes and Russia

So far, European funding has focused mostly on nuclear safety, the destruction of chemical weapons and the redirection of scientists via the ISTC and the STCU, with a small amount of funding being provided for other threat reduction efforts. The most promising avenue would be an expansion of funding for cooperative threat reduction

[197] Roffey, R., 'Biosecurity measures', Presentation to the Conference on The Gulf as a WMD-Free Zone, Stockholm, 30–31 May 2005.

[198] United Nations, Study on Disarmament and Non-proliferation Education (Japan and Sweden key proponents), Resolution 57/60, 22 Nov. 2002.

under the Common Foreign and Security Policy (CFSP). The EU has its special structure, and security policy is still largely a matter for the Member States under the first pillar. There is a need to increase effectiveness and strengthen EU coordination in some form (common strategies, joint actions and so on) and to make the allocation of resources less difficult.

From the European perspective proliferation is understood predominantly in a regional context, for example, proliferation challenges from the Middle East and North Africa. For the EU proliferation should be seen in a broader political, economic and regional context. After the terrorist attacks in the USA in 2001 there is a greater sense in Europe of the urgency of preventing proliferation of WMD. In general Russia is of overriding importance in foreign relations for the whole EU but also for non-proliferation support.

The EU is making an effort to emerge as a global player, not least with the European Security Strategy and the WMD Strategy. In line with this *the EU should enhance its profile and take on a more leading role in setting policy for proliferation prevention in the biological area worldwide*. The EU possesses many unique capabilities and can use a wide range of political and economic (trade, health, development and R&D) instruments to help overcome previous difficulties for CTR activities in the biological area and support its objectives to prevent proliferation. There is a need for a comprehensive and a more concrete long-term strategy for EU non-proliferation policy in this area in order to be able to list priorities and guide funding for non-proliferation support. The present situation in the biological area points to a very weak support from the Russian Government for ongoing activities, and political initiatives are needed by the EU to better explain the objectives of non-proliferation prevention work in the biological area.

A constructive and non-confrontational approach is needed. One priority for Russia should be to establish an improved legal basis for cooperation and resolve outstanding issues concerning intellectual property rights and transparency/access. It has been proposed that Russia reach an agreement on an action plan for bio-security with some Western partners, as this could be beneficial for widening cooperation.[199] It can be noted that the EU has already initiated work in this direction. There has been an agreement between the European Commission, several EU Member States and the Russian Ministry of Health, together with the Vector institute in Novosibirsk, to initiate a project to develop improved diagnostic methods for orthopoxviruses. In contrast to the US experience, there have been no problems with contacts with the Russian ministries, although some internal friction could be noted between institutes and the ministerial level in Russia. From the European Commission and the Russian side this has been seen as a first step which can be followed by extended cooperation on other priority pathogens of mutual interest. From the Commission's view point this cooperation can work, as the Russian side has a great deal of know-how on pathogens that would be of value for EU, and for the Russian side it is important to get something in exchange—in this case new techniques and methods from the EU countries involved.[200]

The proposed way forward for Russia could be to focus on those dangerous agents that would be of most interest for potential terrorists and those that pose the greatest risk from the public health perspective. This would mean first agreeing on a common risk assessment of agents and listing them. Such work has been done in the EU, in the Member States and in Russia, so it should be possible find common ground. Based on

[199] Kobyakov and Orlov (note 115).

[200] Gouvras, G., European Commission, DG Health and Consumer Protection, Luxembourg, Personal communication, May 2005.

this, *a survey should be carried out to identify which facilities work with, handle or store priority pathogens and toxins*. This survey should be done in cooperation between Russian and EU experts. Examples of lists of critical biological agents that could be used in a biological attack and, as such pose a risk for national security, have been designed by the EU,[201] the CDC,[202] the WHO[203] or the Australia Group. The survey should identify the type of work carried out, the approximate numbers of scientists engaged, levels of bio-safety and bio-security at such facilities, and need for support. It will be important that common criteria for the evaluation of bio-safety and bio-security are prepared and used in the survey. One result of the survey should also be a national list of where various pathogens are stored, and this could provide a basis for discussing whether there is a need to limit the number of localities where the same type of pathogens are stored for reference purposes.

A similar survey would also be useful among EU Member States. First a decision should be taken to promote and develop bio-security standards inside the EU but also to promote such standards outside the EU. What measures will be needed? Is licensing facilities and/or scientists that work with dangerous pathogens and toxins a realistic option and how could it be done? The EU needs to strengthen national legislation and control over pathogenic micro-organisms and toxins (both in Member States and in acceding countries) where necessary. This could then be the basis for cooperation with Russia and the NIS on the issue of bio-security.

In proliferation prevention programmes, bio-safety and bio-security measures will play a vital role. They should involve an oversight system for physical protection of dangerous pathogens, dual-use technologies and facilities, and measures to prevent theft, illicit sale or transfer and accidental release of pathogens. They should promote the implementation of security regulations, safety training, the possibility of licensing facilities, standards of practice in the workplace and personnel vetting.[204]

Many Russian and NIS civilian facilities that possess dangerous pathogen culture collections or toxins and dual-use production equipment have received little or no outside assistance. Many facilities are still in need of help to make long-term transitions from previous work to focusing on civilian and public health applications. One problem is that if certain levels of standards are set for bio-safety and bio-security many facilities will not be able to achieve those standards without assistance. To achieve a more focused approach to areas of specific support and assistance the EU should consider whether separate centres of excellence devoted primarily to promoting bio-safety and bio-security, including research and training, would enhance efficiency. It can be proposed that such a centre should have its focal point at the CDC, with subsidiary laboratories for implementation and training in Russia, for example, at TEMPO, as well as in the NIS or other countries of concern. The aim could be to promote common standards and initiate a culture of bio-safety and bio-security at institutes involved in work on dangerous pathogens. Potentially such centres of excellence could be engaged also in non-proliferation training in the biological area.

The most practical avenue for cooperative R&D for this new effort would still be to channel increased support through the reformed ISTC and STCU for funding bio-

[201] European Commission, 'Case definition for bio-terror agents', Doc. 2003/534/EC, Brussels, 17 July 2003; and Council of the European Union, Regulation (EC) no. 1504/2004 (in force since 30 Sep. 2004), *Official Journal of the European Union*, L281, 31 Aug. 2004.

[202] 'Biological and chemical terrorism: Strategic plan for preparedness and response. Recommendation of the CDC Strategic Planning Workgroup', MMWR Morb Mortal Wkly Rep, 2000, 49 (RR-4), pp. 1–14.

[203] *WHO Public Health Response to Biological and Chemical Weapons*, 2nd en., 2002 <http://www.who.int/emc/book 2nd edition.htm>.

[204] Averre, Luongo and Martellini (note 64).

technology and life science programmes. Today each funding partner has its own criteria and in some cases these have been shared with another partner. There is a need for a more coordinated view and well-specified criteria for funding. The funding partners should be more focused and list priorities for the type of work being done, and should be clear which of the priority categories above would be the basis for approving research proposals. This would involve much more active participation from funding partners, and also benefit funders as they would have better insight, understanding and possibilities to influence the research so that cooperation becomes more active.

Complementary to the ISTC and the STCU, *a new organization should be considered to channel EU support outside the FSU* that should be tailored in accordance with the priorities set by the EU for non-proliferation support. This would then be the EU centre for non-proliferation support, R&D, training and exercises. It would also achieve the goal of establishing a clear EU point of contact for these kinds of issues.

There is a need for an overall framework in the EU for planning and setting priorities for proliferation prevention or CTR-type activities. Most of this is today a question for Member States, which have not been active in the biological area apart from supporting the ISTC and the STCU. Only recently have the UK, France and to lesser extent Sweden begun to seriously to think of or initiate some small projects. The general feeling is that states are interested to do something in the biological area but they are looking for 'good' projects without defining what these might be or might not be. Time has shown that it is not efficient or sufficient to continue to handle these questions this way. What is needed is a kind of EU 'master plan' for the biological area setting out the political frame but focusing on areas of priority such as bio-safety and bio-security upgrades, epidemiological surveillance, diagnostic capabilities, vaccine development, preparedness planning for natural outbreaks or deliberate releases of biological agents, and environmental problems in or around facilities. As an example, it is extremely unfortunate that no CTR-type activities have been possible to initiate at the Russian anti-plague institutes, although the need is great. The disparate systems for epidemiological surveillance of both human and veterinary infectious diseases at the Russian anti-plague institutes and stations should be strengthened and better integrated with other systems.[205] Preparedness for infectious disease outbreaks is a priority in Russia and the NIS and, given the need to improve disease surveillance systems and connect them internationally, incentives should be provided to public health institutes to play a more active role, develop preparedness and response plans, and improve communication and information sharing.

Commercial opportunities have become more of a focus for threat reduction in the sense of improving infrastructure and capacity building at Russian and NIS facilities so they can 'graduate' and become self-sustaining commercial enterprises. The focus here should be on former BW facilities to convert their industrial capabilities to peaceful purposes. Help is needed for example with realistic business plans, intellectual property rights, patent issues, identifying viable products, identifying markets and training.

Another difficult problem is still *achieving international standards for GMP, GLP, bio-safety and bio-security*. In this area too the EU could benefit from cooperation and would have much to offer. There is a need to establish an oversight system for bio-security, implement regulations that have to be developed, promote a bio-safety/bio-security culture in facilities and initiate training programmes, as well as monitoring work practices, transfers of material and personnel.

[205] Potter, W., Statement at the International Conference "G8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction", Moscow, 23 Apr. 2004 <http://www.pircenter.org/rus/club/steno.html>.

Lack of access is also still a problem, in Russia at least, in the development of commercial opportunities.

A further problem is guaranteeing that there is no residual contamination of agents from previous BW production, and this may not be a simple matter. In many cases this can mean being forced to construct new buildings or buy new equipment to be on the safe side.[206] It has been found that one solution is to establish centres of excellence of interest to foreign investors. Commercialization has, however, been slow, and there has been only limited interest from Western companies and there are few success stories. One aspect of this is that the experience of privatization in Russia has not been positive, resulting in former BW facilities having to close down. Commercialization in the biotechnology area not on the high tech-end but more low-tech might provide more immediate solutions and potential income.[207] The EU could investigate the potential benefits of greater cooperation on civilian biotechnology.[208] The areas in biotechnology, in addition to R&D, would be in the agricultural or food industry rather than the strictly regulated pharmaceutical industry with its large investment needs and long-term strategic plans.

A further aspect is that the EU as yet has only limited administrative capacity to handle and coordinate large CTR activities in the biological area. A careful analysis should be carried out of the potential benefits to the European biotechnology industry of enhancing the engagement in CTR activities in Russia and the NIS. This should take into account various European countries' comparative advantages in specific areas.[209]

It has been difficult to address the issue of cooperation with Russia related to implementing presidential agreements from the beginning of the 1990s,[210] such as President Yeltsin's decree On the Lag in Implementation of International Treaties, which resulted in the Trilateral Agreement and process that broke down in the mid-1990s and has never been followed up. Questions still remain on the status of facilities, equipment and personnel of the previous Soviet BW programme. A full inventory is needed on the scope and location of all BW facilities and institutes in order to fully address the security needs,[211] including greater openness from the Russian side. Further threat reduction in the biological area has to take account of this.[212] A major concern still, however, is that threat reduction programmes have so far not been able to initiate a dialogue, let alone reach the military microbiological facilities subordinated to the Russian Ministry of Defence with support proposals. Scientists at these facilities are still prevented from making international contacts or cooperation. The civilian facilities of the former Soviet BW programme Biopreparat have been opened to foreign aid step by step. In spite of this there is still a marked lack of knowledge about and transparency of the historical, present and future activities at these facilities and Biopreparat.

[206] Ouagrham and Vogel (note 192).

[207] Averre (note 192).

[208] Luongo, K. L., Averre, D., Ratta, R. D. and Martellini, M., 'Building a forward line of defense, securing former Soviet biological weapons', *Arms Control Today*, vol. 34, no. 6 (2004).

[209] Roffey *et al.* (note 38); Roffey R,, 'The legacy of the former Soviet BW programme and need for enhanced support for redirecting to civilian commercial and R&D activities', Presented for Swedish Ministry of Defence at the Workshop on Building a Global Agenda for Bio-proliferation, Current Status and Future of Russian Biotechnology, Como, Italy, 17 18 Nov. 2003; and Roffey, 'Need for enhanced support . . .' (note 192).

[210] Anthony (note 11).

[211] 'Global Partnership scorecard: Strengthening the Global Partnership', May/June 2004, <http://www.sgpproject.org>.

[212] Roffey, R., 'Lessons learnt from the former Soviet BW programme and threat reduction activities', Paper presented at the Workshop on Lessons learned from the Soviet, Iraqi and South African Bio-programmes as well as Bio-terrorist attacks, Institut Français des Relations Internationales, Paris, 20 Sep. 2004.

In a time when the focus is on bio-terrorism, R&D programmes could be initiated to develop improved protection for civilian populations using know-how in the bio-defence sector. Part of this could be projects focusing on measures to secure pathogen collections, the development of rapid identification and detection methods, the development of medical countermeasures, or support to basic research on priority pathogens.

The EU programme on protection against NBC terrorism could be a vehicle to initiate cooperation.[213] Joint R&D programmes could be initiated to develop improved protection for civilian populations using know-how in the Russian bio-defence sector. The EU could sponsor workshops and seminars where the bio-defence/bio-terrorism communities could meet and discuss cooperation more in detail. There would also be a need for an umbrella agreement between the EU and Russia to cooperate on protection against bio-terrorism. An activity in this area could have commercial possibilities and could also be confidence-building. This cooperation should be wider than only including Russia and also cover the NIS or other states.

It has to be discussed how funding from several EU pillars can be achieved: for example, funding for public health, food safety, export control, research and law enforcement could all support proliferation prevention projects. There is an urgent need to look at potential mechanisms by which such multi-purpose cooperation could be achieved keeping the non-proliferation aims of the activities. A broad political discussion will be needed involving several political areas to find a new and improved EU policy on cooperative proliferation prevention. A substantial increase in EU funding for the biological area is recommended in order to achieve important non-proliferation aims also in this area in addition to the nuclear and chemical areas. There is a need for a stronger coordination for proliferation prevention activities to foster better coordination between the EU's three pillars and increase effectiveness and the evaluating capabilities.

Improved coordination is also needed between the main donors, and between donors and recipient countries and organizations. A special EU coordinator could be appointed. Greater European involvement in a multilateral effort would bring political advantages, as there is still some resistance in Russia to US involvement. One option could be to expand the scope of the EU Joint Action for Russia to coordinate non-proliferation prevention activities in the biological area, and there is a need for an active long-term EU strategy in this area on a global scale. There is then also a need for a more in-depth analysis of previous threat reduction activities carried out in the biological area in the last 10 years, and of their strength and weaknesses, in order to evaluate whether the goals set up for different donors and agencies have been achieved and to see what lessons could be learned for the future. This especially so if the EU aims to initiate a well-focused programme that could achieve important non-proliferation goals.[214]

Recommendations for European Commission/Council action

- Carry out a study in the EU Member States of the number of laboratories, institutes or commercial enterprises with culture collections with high-risk

[213] Council of the European Union, 'Adoption of the programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats', DG I, 14627/02, Brussels, 21 Nov. 2002.

[214] Roffey, R., 'The legacy of the former Soviet BW programme and need for enhanced support for redirecting to civilian commercial and R&D activities', Presented at the Workshop on Building a Global Agenda for Bio-proliferation: Current Status and Future of Russian Biotechnology, Como, Italy, 17–18 Nov. 2003; and Roffey, 'Need for enhanced support . . . ' (note 192).

pathogens or toxins and/or that work with such agents, including their level of bio-safety/bio-security.

- Develop EU guidelines for bio-security that complement bio-security measures taking note of WHO work in this area.
- Initiate a study on the possible creation of a centre of excellence on collaboration on bio-security and bio-security training, as well as supporting epidemiological surveillance training, affiliated to the ECDC.
- Develop the guidelines and priorities for EU cooperative proliferation prevention programme in the biological area in line with the proposals in this report, indicating priority areas of activity and geographical priorities.
- Develop specific proliferation prevention criteria for selection of projects for ISTC or STCU funding. These criteria should be openly declared so that interested scientists and facilities can see what type of projects EU would primarily fund.
- Initiate a worldwide study together with the WHO on facilities that have or work with dangerous pathogens or toxins, including level of bio-safety/bio-security, in accordance with agreed guidelines and an agreed select agent list.
- Carry out similar detailed study in cooperation with Russia and the NIS.
- Open a dialogue with the Russian Government for a cooperative proliferation prevention programme in the biological area. This would be part of a long-term strategy involving financial and political commitment on both sides to prevent proliferation, with the focus on technology and institutes of most concern, in supporting public health, R&D, biotechnology development, agriculture, the environment, and potential commercial collaboration.
- Initiate similar dialogues with the NIS and other states for EU cooperative proliferation prevention programmes.
- Promote more active collaboration in the biological area within the framework of the Global Partnership, and press for a memorandum or implementation agreement with Russia in the biological area.
- Press Russia to allow its Ministry of Health and Social Development anti-plague institutes and Ministry of Defence facilities to participate in Global Partnership cooperation.
- Examine the case for an EU coordinator, including a centre for proliferation prevention support programmes, to channel support outside the ISTC/STCU areas, for better coordination and as a focal point for these issues.