Improving Implementation of the Biological Weapons Convention

The 2007–2010 Intersessional Process

Piers Millett editor

UNIDIR/2011/7

Improving Implementation of the Biological Weapons Convention

The 2007–2010 Intersessional Process

Piers Millett
Editor

UNIDIR
United Nations Institute for Disarmament Research
Geneva, Switzerland

UNODA
United Nations Office for Disarmament Affairs
Geneva, Switzerland

UNITED NATIONS

New York and Geneva, 2011

About the cover

NOTE

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delimitation of its frontiers or boundaries.

*
* *

The views expressed in this publication are the sole responsibility of the individual authors. They do not necessarily reflect the views or opinions of the United Nations, UNIDIR, its staff members or sponsors.

UNIDIR/2011/7

UNITED NATIONS PUBLICATIONS

The United Nations Institute for Disarmament Research (UNIDIR)—an autonomous institute within the United Nations—conducts research on disarmament and security. UNIDIR is based in Geneva, Switzerland, the centre for bilateral and multilateral disarmament and non-proliferation negotiations, and home of the Conference on Disarmament. The Institute explores current issues pertaining to the variety of existing and future armaments, as well as global diplomacy and local tensions and conflicts. Working with researchers, diplomats, government officials, NGOs and other institutions since 1980, UNIDIR acts as a bridge between the research community and governments. UNIDIR's activities are funded by contributions from governments and donor foundations.

www.unidir.org

CONTENTS

FOREWORD

The Biological Weapons Convention (BWC) is one of the three pillars of international efforts to eliminate weapons of mass destruction, a United Nations goal since 1946. The BWC states parties have undertaken great efforts to consolidate the convention's implementation and build national capacity to prevent disease and life science capability from being used to cause harm.

Between the Fifth and Sixth, and the Sixth and Seventh Review Conferences, and through two consecutive sets of meetings, the regime has been actively addressing efforts—ranging from exploring the interface between health and security, responding to the possible use of a biological weapon, through to building relevant national capacity. Most significantly, a growing community of stakeholders and experts has contributed to these Intersessional Processes.

Modern biology is broadly distributed both geographically and through different sectors of societies. Ensuring that it continues to be used solely for peaceful purposes is a challenge that will undoubtedly require a multi-track, multi-faceted and multinational approach. The way that the BWC has repositioned itself to take advantage of the broader community that now supports its work offers much promise for the continued efficacy of the regime into the future. This work embraces both the participation and contributions of technical experts from a broad range of countries, case studies of national experiences and reflections from the field. Increasingly, the knowledge and expertise needed to prevent the misuse of the life sciences is found in a growing number of governmental agencies as well as in professional societies, technical bodies, academia and the private sector.

It has been said that:

> there's no real evidence that one can become expert in something as broad as "decision making" or "policy" or "strategy". … [T]hese are skills that yield to application, hard work, and native talent. … And much of what we've seen so far suggests that a large group of diverse individuals will come up with better and more robust forecasts and

> make more intelligent decisions than even the most skilled "decision maker".[1]

This book charts the story of both the work of the BWC in the lead up to the Seventh Review Conference and the important steps in its ongoing evolution to address biological risks and threats in the twenty-first century. The lessons it contains are important tools for all those with a stake in the future of the life sciences. The book will help states parties prepare for the Review Conference, provide a valuable reference guide for national contact points, and contribute to the shaping of arms control, disarmament and non-proliferation regimes in the future.

Sergio Duarte
United Nations High Representative for Disarmament Affairs

Theresa Hitchens
Director
United Nations Institute for Disarmament Research

1 J. Surowiecki, *The Wisdom of Crowds*, 2005, p. 32.

ABOUT THE AUTHORS

Austin Ochieng Aluoch is Chairman of the National Biological and Toxin Weapons Committee (NBTWC). The NBTWC is set up under the National Council for Science and Technology, which is Kenya's Biological Weapons Convention (BWC) Focal Point. The NBTWC is tasked with drafting biosecurity legislation in Kenya, submitting confidence-building measure forms and enhancing Kenya's biosecurity status. Dr. Aluoch has served as Chairman since its establishment in 2009. He has a doctorate in bioanalytical chemistry from the State University of New York. Dr. Aluoch also holds a certificate in dual-use biosecurity education from the University of Bradford, and has participated in several training workshops on biosecurity, including a leadership course in biosecurity/biosafety planning and implementation at Brooks City Base, San Antonio. He is a regular representative of the Kenyan delegation to the BWC Intersessional Process. His research interests include the development of biosensors for the detection of biological pathogens, and he has several publications in the field of biosensors, including a review for the US Department of Homeland Security on "Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders". He recently spearheaded the drafting of Kenya's biosecurity policy and is currently involved in drafting Kenya's biosecurity bill.

Georgi Avramchev is now engaged in business development consulting and participated in founding Eco Energy Ltd., a renewable energy developer and system integrator of wind and photovoltaic electricity production. From February 2005 through July 2009 Ambassador Avramchev was Permanent Representative of the former Yugoslav Republic of Macedonia to the United Nations Office and the Other International Organizations in Geneva, and the World Trade Organization (WTO). During his tenure at Geneva as nominee of the Eastern Group, he was elected by the states parties to chair the 2008 BWC meetings. In 2004, prior to his posting at Geneva, he was engaged with the Minister of Economy of the former Yugoslav Republic of Macedonia as his Special Advisor on International and Multilateral Trade, including trade policy, WTO and trade-related intellectual property issues, spending one year at the Ministry of Economy. Before that he acquired vast and diversified managerial experience working for over 20 years in the private sector, both as an entrepreneur

and manager, holding high managerial posts in the manufacturing and construction industry, international and domestic trade, insurance and management consulting. In 1975 Ambassador Avramchev obtained a bachelors in business administration from DEREE College, at the American Colleges of Greece. He earned his masters in business administration in 1978 at the Northeastern University, in Boston.

Joris De Baerdemaeker has been Manager of the International Criminal Police Organization (INTERPOL) Bioterrorism Prevention Programme since December 2008. This programme develops training for law enforcement and public health, encourages the enforcement of existing legislation and promotes inter-agency cooperation for the prevention and response to bioterrorism. Prior to joining INTERPOL he worked at the Counter-Terrorism Unit of the Federal Police in Belgium, responsible for the prevention and response to chemical, biological, radiological and nuclear (CBRN) terrorism. This included the responsibility of the investigative policy and procedures related to CBRN preparedness, developing and implementation of countermeasures as well as training police staff. He also worked as a policy advisor at the International Police Cooperation division at the Federal Office of Police, Switzerland, and has an extensive background on operational police work as a former local police commander in Antwerp. Mr. De Baerdemaeker holds a masters in communication sciences and is currently following the Certificate in Terrorism Studies at the University of St Andrews. He has followed senior police training focusing on management in police functions as well as extensive CBRN training within military and police forces.

Cathy Bollaert trained as a biochemist in South Africa. She completed a masters in peace and conflict studies at the University of Bradford. Currently, she is working for the Bradford Disarmament Research Centre where she is a research associate responsible for the development and delivery of postgraduate and short courses in online academic teaching in dual-use biosecurity and bioethics education.

Katherine Bowman is Senior Program Officer with the Board on Life Sciences of the National Research Council (NRC) of the National Academy of Sciences. She manages studies and activities across a range of life sciences topics, and participates in NRC activities addressing the potential implications of developments in science and technology. She previously served as a programme officer with the NRC Board on International

Scientific Organizations, where she worked with international scientific unions in the biological sciences, chemistry and radio science. Prior to this she was a Christine Mirzayan Science and Technology Policy Fellow at the NRC, working on biosecurity issues. Dr. Bowman received her bachelors in biology from Amherst College and her doctorate in biomedical engineering from Johns Hopkins University.

Koos van der Bruggen originally studied political science. Prof. van der Bruggen wrote his doctoral thesis on the ethical judgment of nuclear deterrence. He has been working for the Dutch organization for technology assessment. More recently he has been involved in developing a code of conduct for scientists regarding biosecurity. At the moment he is working for the Delft University of Technology. Some recent publications include "Science of Mass Destruction: How Biosecurity Became an Issue for Academies of Science" and "Possibilities, Intentions and Threats. Dual Use in the Life Sciences Reconsidered".

Teck Mean Chua is President of the Asia–Pacific Biosafety Association. Dr. Chua is also Laboratory Consultant at Temasek Life Sciences Laboratory at the National University of Singapore. He has served as a temporary technical adviser to the World Health Organization (WHO) Biosafety Advisory Group and has also served at the WHO as a short-term consultant to assist in laboratory capacity-building in Indonesia and Mongolia for high containment facilities as part of its preparedness in responding to any outbreaks.

Robin Coupland is a medical adviser to the International Committee of the Red Cross (ICRC). Dr. Coupland joined the ICRC in 1987 and has worked as a field surgeon in Afghanistan, Angola, Cambodia, Kenya, Pakistan, Somalia, Sudan, Thailand and Yemen. He has developed a health-oriented approach to a variety of issues relating to the design and use of weapons. A graduate of the School of Clinical Medicine, University of Cambridge, he trained as a surgeon at the Norfolk and Norwich University Hospital and University College Hospital, London. He became a Fellow of the Royal College of Surgeons in 1985. He has a graduate diploma in international law from the University of Melbourne. As part of his current position he has focused on the effects of weapons both conventional and non-conventional. Dr. Coupland has developed a public-health model of armed violence and its effects as a tool for policymaking, reporting and communication. His current work has two tracks: first, the feasibility of

an ICRC operational response in the event of use of chemical, biological, radiological or nuclear weapons, and improving security of health care in armed conflicts. He has published medical textbooks about the care of wounded people and many articles relating to the surgical management of war wounds, the effects of weapons and armed violence.

Malcolm Dando trained originally as a biologist. He has a bachelors and doctorate from the University of St Andrews and after post-doctoral research in the United States worked in operational research for six years in a Ministry of Defence funded project at the University of Sussex. Prof. Dando moved to the Department of Peace Studies, University of Bradford in 1979 and has worked on arms control and disarmament issues since then. His research since the early 1990s has been on the BWC. Most recently he has been involved in efforts to develop teaching materials related to the convention for life scientists.

Isabelle Daoust-Maleval has a doctorate in biochemistry from the University Pierre et Marie Curie in Paris. Dr. Daoust-Maleval has managed research teams and carried out teaching and training courses at the university level. She was scientific advisor on biological and chemical issues at the General Secretariat for Defence and National Security (Prime Minister's Office), in France. She is head of the non-proliferation and disarmament office at the Ministry of Defence Department for Strategic Affairs. Specializing in security, defence and risk management, Dr. Daoust-Maleval has been involved with numerous international negotiations and is a member of several expert panels. She has been appointed chevalier de la Légion d'honneur and chevalier de l'Ordre national du Mérite.

Katsuhisa Furukawa is a Fellow of the Research Institute of Science and Technology for Society at the Japan Science and Technology Agency. Mr. Furukawa is in charge of a project on science, diplomacy and security. Since 2006 he has also been a member of the Council for Asian Transnational Threat Research and a lecturer for the UN Security Council resolution 1540 Committee Regional Workshop. He holds a bachelors degree in economics from Keio University and a masters in public administration from the Harvard Kennedy School at the John F. Kennedy School of Government.

Louise Gresham brings expertise in national and international disease surveillance systems in the Mekong Basin, the Middle East, the US–Mexico

border and Southern Africa. She is part of a health diplomacy consortium in the Democratic People's Republic of Korea. Dr. Gresham convenes and secures commitments from international leaders, most recently to create the ambitious global organizational structure, Connecting Organizations for Regional Disease Surveillance. She has nurtured public private partnerships in support of regional disease surveillance efforts and is a member of the Center for the Study of Weapons of Mass Destruction Advisory Board. She has extensive experience managing infectious disease surveillance and response activities and policymaking, having served as Senior Epidemiologist for the Health and Human Services Agency of the County of San Diego. Dr. Gresham holds an adjunct associate professor appointment at the Graduate School of Public Health, San Diego State University, and is well published in peer-reviewed journals and texts.

Marius Grinius joined the Canadian Foreign Service in 1979 after 12 years of military service in the Canadian army. Ambassador Grinius has had two postings to Thailand, one to the Canadian Delegation to the North Atlantic Council, and two postings to Viet Nam, the second as Ambassador. His tours of duty at the Department of Foreign Affairs and International Trade Canada, in Ottawa, including desk officer for nuclear arms control, and as Director of the Asia Pacific South and then Southeast Asia divisions. More recently he has had a series of assignments in Ottawa, including in the Privy Council Office as principal analyst in the Social Development Policy Secretariat, Director of Operations in the Security and Intelligence Secretariat, as well as Director-General of Operations in the Department of Western Economic Diversification. After concluding his tour as Ambassador to the Republic of Korea and to the Democratic People's Republic of Korea, he was posted as Ambassador and Permanent Representative to the United Nations Office at Geneva and to the Conference on Disarmament. Ambassador Grinius was Chair of the 2009 BWC meetings.

Keith Hamilton is a veterinarian from the United Kingdom. Having worked in mixed animal practice, field disease control programmes and with a non-governmental organization in India, Dr. Hamilton went on to study infectious disease control at the London School of Hygiene and Tropical Medicine, including field work relating to the control of zoonotic African trypanosomiasis in Uganda. In 2003 he joined the UK government to advise on the control of veterinary exotic diseases, and in 2007 was seconded to the World Organisation for Animal Health, where he works

on a range of topics, including laboratory capacity-building, animal influenza, and biological threat reduction.

Marianne Heisz is Director of the Office of Biosafety Programs and Planning with the Pathogen Regulation Directorate, at the Public Health Agency of Canada. In this capacity, Ms. Heisz directs a team responsible for pathogen risk assessment, biosafety training, biosafety regulatory investigation and standards and guidelines, which includes the Canadian *Laboratory Biosafety Guidelines*. Ms. Heisz is also responsible for the human pathogen component of Canada's annual confidence building measures under the Biological Weapons Convention (BWC), and has been an active participant of the Canadian delegation at BWC Meetings of States Parties, Meetings of Experts and Review Conferences since 2001, due to her specialization in biosafety, biosecurity and regulatory oversight. She holds a masters from the University of Ottawa in microbiology and immunology, and is a regular speaker at conferences around the world on the topic of biosafety and regulatory oversight of human pathogens.

Jo Husbands is Scholar and Senior Project Director with the Board on Life Sciences of the National Research Council, where she manages studies and projects to help mitigate the risks of the misuse of scientific research for biological weapons or bioterrorism and represents the National Academy of Sciences (NAS) on the Biosecurity Working Group of the InterAcademy Panel on International Issues: The Global Network of Science Academies. From 1991 through 2005 Dr. Husbands was Director of the NAS Committee on International Security and Arms Control and its Working Group on Biological Weapons Control. Before joining the NAS she worked for several Washington, DC-based non-governmental organizations focused on international security. She is currently an adjunct professor in the Security Studies Program at Georgetown University. She holds a doctorate in political science from the University of Minnesota and a masters in international public policy (international economics) from the Paul H. Nitze School of Advanced International Studies at the Johns Hopkins University.

Ngoc Phuong Huynh completed her masters in international relations at the Graduate Institute of International and Development Studies. She is currently Associate Political Affairs Officer for the Implementation Support Unit (ISU) for the BWC, housed at the United Nations Office for Disarmament Affairs, in Geneva. Her duties include acting as a member

of the Secretariat for all meetings of the BWC since the creation of the ISU in 2007, liaising with international organizations, interacting with states parties to the convention on implementation, universalization and building confidence in the convention regime. She is regularly invited as a speaker, lecturer or chair at various conferences, workshops, training programmes and roundtables around the world, including INTERPOL, the United Nations Interregional Crime and Justice Research Institute, and the 1540 Committee.

Aamer Ikram is a consultant microbiologist and associate professor at Armed Forces Institute of Pathology, Pakistan. Dr. Ikram is a medical doctor, holds a diploma in pathology, Fellowship in Microbiology and a diploma in occupational safety and health, and a diploma in disaster management. During 2005 he received clinical microbiology and infection control training in the United Kingdom. He completed a course in emerging infectious diseases at the University of Iowa in 2010. He has an impressive record of courses from renowned universities such as Bradford, Chester, Harvard, Iowa, Oxford, South Florida, and the Institute of Leadership and Management and workshops from the American Biological Safety Association (ABSA), the United Nations, United States Centres for Disease Control and Prevention and the World Health Organization. He has the honour of being the first Pakistani national to qualify as a registered biosafety professional from ABSA. As part of National Task Force on Biosafety, Ministry of Foreign Affairs, Pakistan, he has contributed to the formulation of BWC-related legislation and the "National Guidelines for Codes of Conduct for Life Scientists". He has represented Pakistan at the BWC meetings in Geneva a number of times. He has also been part of group working on confidence-building measures within the Geneva Forum. He is among the founding members of the Biological Safety Association of Pakistan and is also member of ABSA and the European Biosafety Association. He has significantly contributed towards raising awareness about biosafety and biosecurity in Pakistan. He is Chief Editor of *Infectious Diseases Journal of Pakistan*, Associate Editor of the *Pakistan Journal of Pathology*, and has large number of research publications to his credit.

Masood Khan is the Pakistan Ambassador to China, a post he has had since 2008. Prior to his current assignment, from 2005 through 2008, Ambassador Khan was the Permanent Representative of Pakistan to the United Nations and Other International Organizations in Geneva and

also the Pakistan Ambassador to the Conference on Disarmament. Earlier Ambassador Khan worked as Foreign Office Spokesman in Islamabad, and as Director-General (United Nations), Director-General (Disarmament) and Director-General (East Asia and Pacific). In the 31 years of his diplomatic career, he has also served in Beijing, New York (Permanent Mission to the United Nations), Washington and The Hague. He specializes in security and disarmament issues, and has long experience in multilateral diplomacy. In 2005, in his capacity as Committee Chair, he helped resolve the issue of Internet governance during the World Summit on the Information Society. He was President of the 65-member Conference on Disarmament from June through August in 2005. In 2006 Ambassador Khan, as President of Sixth Review Conference of the Biological Weapons Convention (BWC), steered it to a successful conclusion. He was also the Chairman of the BWC meetings in 2007.

Richard Lennane is Head of the Implementation Support Unit, which was established by the Sixth BWC Review Conference in 2006. Previously, he was a member of the BWC meetings secretariat in the Geneva Branch of the United Nations Office for Disarmament Affairs, where he was responsible for organizing BWC meetings and tending to the administrative needs of the convention and its states parties. He has been secretary of a number of BWC meetings, including the Fifth Review Conference, in 2001, and the Sixth Review Conference, in 2006. Before joining the United Nations in 2001, he was a diplomat in the Australian foreign service, and from 1998 through 2001 was a member of the Australian delegation to the Ad Hoc Group negotiations on a verification protocol for the BWC.

Robert Mathews is Head of NBC Arms Control in the Human Protection and Performance Division of the Australian Defence Science and Technology Organisation. Dr. Mathews served as Scientific Adviser to the Australian Delegation to the Conference on Disarmament from 1984 until 1992. Since 1993 he has provided scientific support to the Australian delegation to the Organization for the Prohibition of Chemical Weapons (OPCW), based at The Hague. He has also provided support to Australia's efforts towards to non-proliferation of weapons of mass destruction (WMD), including support for the Australia Group export licensing measures since its inception in 1985, and in the efforts to develop a verification protocol and other methods to strengthen the BWC. More recently he has become involved in the application of various counter-proliferation measures and Security Council resolution 1540 as a means to raise the barriers to terrorist

groups acquiring WMD. Since 1991 he has collaborated with the Faculty of Law at the University of Melbourne on various scientific and legal aspects of arms control. In 2001 he was appointed to the Advisory Board of the Asia Pacific Centre for Military Law at the University of Melbourne, and in 2002 he was appointed Principal Fellow and Associate Professor of the Faculty of Law at the University of Melbourne. In 2004 he was appointed to the OPCW Scientific Advisory Board, and in 2006 he was appointed to the Informal Board of Experts of the INTERPOL Bioterrorism Prevention Programme.

Piers Millett is Deputy Head of the Implementation Support Unit, housed at the United Nations Office for Disarmament Affairs, in Geneva. His duties there include acting as Deputy Secretary to BWC meetings, liaising with international, regional and expert bodies as well as implementation, universalization and building confidence in the convention regime. He has served as a member of the Secretariat for all meetings of the BWC since 2001. He trained originally as a microbiologist and is still a Chartered Biologist with the Society of Biology. Dr. Millett has a doctorate from the University of Bradford on the past, present and future of anti-animal biological warfare, which focused heavily on the impact of developments in the life sciences on biological weapons. He also holds postgraduate degrees in international politics and security studies, as well as research methodology. He is widely published on issues related to preventing the acquisition and use of biological weapons and is a regular speaker at conferences around the world.

Kazuaki Miyagishima studied medicine at the University of Tokyo and obtained an international diploma of public administration from the École nationale d'administration. After having served as Medical Officer at the Japanese Ministry of Health and Welfare, he worked as a scientist in the Food Safety Programme at the World Health Organization (WHO) from 1994 through 1998. Subsequently, Dr. Miyagishima held positions of Associate Professor in public health and health policy at Kyoto University (1998–2003) and Secretary of the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and the WHO (2003–2009), before being appointed Deputy Director General of the World Organisation for Animal Health.

Ali Mohammadi has a doctorate in medical microbiology from University College London, with majors in biotechnology and genetic engineering.

Dr. Mohammadi spent most of his career in combating communicable diseases. He was President of the Razi Vaccine and Serum Research Institute in Iran and was also responsible for the research and production of the first avian influenza vaccine in the Middle East. Dr. Mohammadi has also held several positions at the World Health Organization (WHO), which brought him into regular contact with many different programmes on issues ranging from vaccine production, through neglected diseases, good laboratory practice and laboratory biosafety, to disease eradication. His last position at the WHO was Coordinator of Laboratory Alliance and Biosafety. He also managed the WHO-European Union Joint Action on Regional and National Capacity Building on Biorisk Management. Dr. Mohammadi has been involved in development and negotiations of various international conventions, including the BWC, the Chemical Weapons Convention and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. He retired from the WHO in December 2010 and now acts as a consultant. He is founder and president of a consulting agency on public health and biological risks.

Randall Murch is Adjunct Professor at Virginia Polytechnic Institute and State University. During his first career at the US Federal Bureau of Investigation, Prof. Murch held several positions in the forensic laboratory. In 1996 he created the US programme for weapons of mass destruction forensic investigation and attribution—the first of its kind. He has published in the field of microbial forensics and presented widely, including recently to international audiences. He has also served on several National Academy of Sciences boards and study committees, two of which have focused on aspects of forensic science. His docorate is in the life sciences.

Maurice Owuor Ope is currently the medical epidemiologist at the East African Community (EAC) Secretariat in Arusha, Tanzania. Dr. Ope is currently involved in the coordination of the initiation and implementation of various regional disease prevention and control policies, legislation, strategies and programmes targeting priority communicable diseases and non-communicable diseases in the five EAC partner states of Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania. His recent publications include “High Mortality in a Cholera Outbreak in Western Kenya After Post-Election Violence in 2008”, which appeared in the *American Journal of Tropical Medicine and Hygiene* in 2009, and “Risk Factors for Hospitalized Seasonal Influenza in Rural Western Kenya”, which appeared in *PLoS ONE* in 2011.

Pedro Oyarce is a lawyer and a career diplomat. Posts held during the last 10 years by Ambassador Oyarce include Director of Multilateral Policy at the Chilean Foreign Office, Permanent Representative to the Organization of American States in Washington and since 2010 Permanent Representative to the United Nations in Geneva. In 2010 he was Chair of the BWC Meeting of Experts and Meeting of States Parties. In February and March 2011 he was Chair of the Conference on Disarmament. Ambassador Oyarce is a specialist in the law of the sea and international human rights. His recent publications have focused on the Inter-American Democratic Charter, the Inter-American Human Rights System as well as the United Nations.

Graham Pearson is Visiting Professor in international security in the Division of Peace Studies at the University of Bradford, where he is active particularly in the area of biological and chemical weapons arms control. Prof. Pearson was previously Director General of the Chemical and Biological Defence Establishment, Porton Down, from 1984 through 1995. He is a Fellow of the Royal Society of Chemistry and a member of the Harvard Sussex Program Advisory Board. He has chaired two International Union of Pure and Applied Chemistry (IUPAC) task groups. Prof. Pearson has recently published several Bradford Review Conference Papers and is currently engaged in preparing the Key Points for the Seventh Review Conference. As a representative of the IUPAC, he participated as a guest at the BWC Meeting of Experts in Geneva on 18–22 August 2008.

Leslie Pray is an independent science writer and communication consultant based in Los Angeles, California. Dr. Pray has written extensively on biotechnology, genetics, infectious diseases and public-health policy for the American Chemical Society, Harvard Medical School, Nature, Science, The Scientist, the US Agency for International Development, the US Institute of Medicine and many others. She received her doctorate in population genetics from the University of Vermont and her bachelors from the University of California. An elected member of Sigma Xi, she has been the recipient of numerous scientific research awards, including the American Society of Naturalists Young Investigator Award and the National Science Foundation Environmental Biology Postdoctoral Fellowship.

Brian Rappert is Professor of Science, Technology and Public Affairs in the Department of Sociology and Philosophy at the University of Exeter. Prof. Rappert's long-term interest has been the examination of how choices can

be, and are, made about the adoption and regulation of security-related technologies, particularly in conditions of uncertainty and disagreement. His books include *Controlling the Weapons of War* (2006), *Biotechnology, Security and the Search for Limits* (2007), *Technology and Security* (2007), *Biosecurity* (2009). His book *Experimental Secrets* (2009) offers a novel approach for investigating and writing about the place of absences in social inquiry. In 2010 Prof. Rappert edited a collection about education and biological weapons entitled *Education and Ethics in the Life Sciences*.

Ben Rusek works as a programme officer for the Committee on International Security and Arms Control (CISAC) at the National Academy of Sciences (NAS) on issues related to nuclear and biological non-proliferation and arms control and the misuse of science and technology. He manages the CISAC interaction with its counterpart in Beijing, China. CISAC programmes examine threats related to biological weapons and dual-use biotechnology. Outside of the NAS he is Chair of the Executive Board of International Student Young Pugwash. He has political science degrees from the Ohio State University and Purdue University.

Barbara Schaal is Vice-President of the National Academy of Sciences (NAS) and the Mary-Dell Chilton Distinguished Professor of Biology at the Washington University, St Louis. Her career as a leading evolutionary biologist began with a fascination with plants. She is recognized for her work on the genetics of plant species, particularly for her studies that use DNA sequences to understand evolutionary processes such as gene flow, geographical differentiation, and the domestication of crop species. Born in Berlin, Germany, Dr. Schaal grew up in Chicago, graduated from the University of Illinois with a degree in biology, and received her doctorate from Yale University. She was on the faculty of the University of Houston and the Ohio State University before joining Washington University. Dr. Schaal has been President of the Botanical Society of America and President of the Society for the Study of Evolution. In 2005 she became the first woman elected to the vice-presidency of the NAS.

Scott Spence is Senior Legal Officer at the Verification Research, Training and Information Centre and works primarily in the National Implementation Measures Programme. He coordinates the technical and policy components of the programme with Angela Woodward. This includes supervision of a global review and analysis of national implementation measures for the BWC and, by extension, the biological

weapons-related provisions of Security Council resolution 1540. He is also leading assistance activities, including workshops, with the objective of assisting governments to prepare draft legislation to implement both the BWC and Chemical Weapons Convention. He is also a senior legal expert for the United Nations Interregional Crime and Justice Research Institute and the chemical, biological, radiological and nuclear Centres of Excellence of the Joint Research Institute.

Simon Whitby is Director of the Bradford Disarmament Research Centre (BDRC). His research interests are in the area of biological non-proliferation, dual-use biosecurity and dual-use bioethics. Dr. Whitby is responsible for oversight of the implementation of BDRC project obligations, finance, funding, staffing, reporting requirements and capacity-building. He is also responsible for the development and expansion of BDRC academic and policy-oriented research. He teaches biological non-proliferation and currently delivers online distance learning in dual-use bioethics and biosecurity education.

ACKNOWLEDGEMENTS

Some projects require the lightning fast reactions and burst of speed of a sprinter. Others necessitate the sustained focus and stamina of a long-distance runner. I have worked on this project for five years and am pleased to see that both the long-haul struggles and short bursts of activity have finally borne fruit. I would like to thank everyone who has enthused, encouraged or counselled me along the way—some of whom are mentioned below.

It would not have been possible to bring the results of our collective labours to you without the generous support of the Government of Norway. They supplied the Implementation Support Unit (ISU) with the additional resources that provided the flexibility to produce this text. I wish to thank, in particular, Hilde Janne Skorpen, Snøfrid Emterud and Jon Erik Strømø of the Norwegian Ministry of Foreign Affairs.

There would have also been very little to share without the collective efforts of the chapter authors. I wish to thank them for agreeing to take part in this project—redrafting work they had already presented at Biological Weapons Convention meetings. I was also struck by the efforts many of the authors had to make to comply with the various deadlines throughout this process. The chapter authors signed up for a project that, for some, has meant a long wait to see a final product and many, many promises from me that I really would do something with their text. It has been particularly rewarding to work with such expertise and this project has benefited much from their motivation. I hope that contributing to this project will not prevent you from becoming involved with whatever crazy scheme we come up with next.

Theresa Hitchens, Kerstin Vignard and Ross McRae at the United Nations Institute for Disarmament Research have all helped to ensure that this project produced something that would be of interest and use to a broad audience. This book would not be here without them. Equally, my colleagues at the ISU—Richard Lennane and Ngoc Phuong Huynh—have both not only contributed directly to this project but have had to shoulder the work of the unit whilst I put together this edited volume. This project has also benefited from the support and wisdom of my colleagues at the

United Nations Office for Disarmament Affairs. I would particularly like to thank the High Representative for Disarmament Affairs, Mr. Sergio de Queiroz Duarte as well as Mr. Jarmo Sareva, Director of the Geneva Branch.

Finally, I wish to dedicate this book to my wife Kathryn, who not only makes every day a little bit more special but also inspires me in all I do. Thank you for putting up with my frustration when things did not go quite according to plan.

Piers Millett

CHAPTER 1

INTRODUCTION

Piers Millett

The Biological Weapons Convention (BWC), sometimes known as the Biological and Toxin Weapons Convention, was the first international convention to ban an entire category of weapon. It was a watershed in international disarmament efforts. Negotiators took advantage of an unusual alignment during the cold war to agree a pact in 1972 which effectively bans the development, production, acquisition, transfer, trafficking, stockpiling and use of biological weapons. It went further than any similar piece of international law that preceded it, and thanks to buy-in from major North Atlantic Treaty Organization and Warsaw Pact players, it has a truly global reach. The international community came together to brand these weapons as "repugnant to the conscience of mankind".[1]

The entry into force of this convention should have been the start of a glorious chapter in international peace and security. It was not. Almost as soon as the ink was dry, some of the states parties to the convention were raising questions of compliance. Had all those who ratified it really given up on biological weapons? Had some states retained a production or breakout capacity? These were questions that were to overshadow the work of the convention until the end of the century. Despite decades of investigation, international consensus has yet to be reached on whether it is possible to differentiate between biology and biotechnology being used for peaceful purposes from it being misused to create weapons (let alone how to develop an international regime to identify and deal with those that might be interested in doing this whilst at the same time not placing unrealistic burdens on academia or industry). These questions and the compliance concerns they created continue to be a challenge today.

In reality, the creation of an international convention is not an end to itself. It is an important step towards an international framework that provides tangible security benefits. But to be effective the norm it enshrines must

be respected and the obligations it confers must be implemented. The international community must continue to work hard if a regime is to actually do what it was intended to do. As a result, the actions expected of states parties, if they are to live up to their obligations, can also change over time. Understandings and agreements reached after a convention has been negotiated will alter how states frame it. In part, this book consolidates the understandings reached during the 2007–2010 Intersessional Process and provides, through a series of case studies, concrete examples of how states fulfil their commitments.

The world in which the BWC exists has also changed a great deal since it was created. Some of these changes make the convention even more important. For example, as the life sciences and biotechnology spread around the globe, the potential that they will be used to cause deliberate harm also increases. Other changes have not worked in favour of international treaties. For example, the collapse of the balance of power between two competing superpowers during the cold war decentralized power relationships and started a process that would necessitate engaging a much broader range of stakeholders. The concept of a state being a unified single entity was called into question, and recent BWC experiences highlight the importance of finding ways to better engage separate agencies, groups and sectors within states. The nature of the threats that the convention addresses has also changed—for example, the possibility of a sub-state actor acquiring or using biological weapons was a topic of academic debate before the turn of the century (with the prevailing opinion being that the technological hurdles were too great for such groups to overcome) but was settled at the turn of the century with the anthrax letter attacks in the United States. This book also examines some of the approaches used under the BWC to address these changes—from closer ties with the scientific community to work on the dissemination of the technology, through strengthening working relationships with sectors such as health, agriculture and law enforcement, to the development of biosafety and biosecurity measures to regulate the accessibility of dangerous pathogens within states.

The BWC has had to evolve to confront the challenges of securing biology in the twenty-first century. This change has been embodied by the convention's two most recent work programmes. The first ran from the end of the Fifth Review Conference, in 2002, until the Sixth Review Conference, in 2006. The second ran from the Sixth Review Conference

until the Seventh Review Conference, in 2011. Details of the most recent Intersessional Process are contained in Chapter 2. These work programmes differ from the previous work of the BWC and were unusual for a disarmament and non-proliferation settings. They were described by the Secretary-General in 2006 as "multilateralism as it should be: flexible, responsive, creative and dynamic; and above all focused on overcoming obstacles and delivering results".[2]

Whilst the convention's evolution is not complete, significant progress has been made in strengthening the regime. Rather than trying to negotiate new binding obligations (work that consumed most of the 1990s without yielding any returns), BWC states parties began to focus—largely through necessity—on how to improve the implementation of those obligations they had already made. This is a task that is usually the responsibility of a convention's international organization. However, the BWC has no dedicated international organization. As a result, states parties have had to explore how they can work together and with other partners to find a different working methodology. This book also describes that process.

SECURING THE LIFE SCIENCES AT THE START OF THE 21ST CENTURY

How a relatively obscure disarmament and non-proliferation convention is implemented is probably not the most exciting topic for a book. This does not mean that it is not important. That the work is unlikely to appeal to the general reader does not prevent it from being interesting or useful. For those of us who spend some, or all, of our time thinking about how the regime to prevent the hostile use of the life sciences should be strengthened, the information in this volume should be important, interesting and useful. There might also be something of value for similar thinkers in other arms control, disarmament and non-proliferation fields, as well as those interested in the broader international security environment.

This is the story of the work of the BWC between 2007 through 2010. It is a single source for authoritative information on key issues confronting this part of the security community. The text draws upon some of the best expertise the world has to offer, and provides details of best practices and approaches adopted by states, professionals, experts and practitioners. It is short enough to act as a handy reference guide for those working on these

issues inside government, and at the same time it is substantial enough to provide practical guidance for those who work in the field.

This volume is a compilation of contributions made at BWC meetings from 2007 through 2010. Each chapter reflects the author's contribution to a specific meeting. Individually, they represent the views of some of the world's foremost experts in the diverse range of topics covered. I hope that, collectively, they come together to provide a real flavour of the work of the BWC during these years. While every effort has been made to avoid the contributions being dated, certain details, such as treaty membership, may have been superseded by subsequent events. This is far from an exhaustive collection. The selection of individual contributions was a difficult task and it would have been possible to compile a multi-volume work. The chapters that follow were selected because they provoked interaction, reflected the tone of a meeting or seemed to me to encapsulate the discussions that took place.

If it is possible for an edited volume with around 30 contributors to have recurring themes, then those in this book focus on how we come to terms with the reality of the world in which we find ourselves, how we shape our international architecture to best fit those realities, and how we do more with less in our efforts to strengthen international peace and security.

Small steps, giant leaps and the BWC

Prior to working through the Intersessional Processes, BWC states parties had spent almost a decade trying to negotiate a single large text that would address all the major outstanding challenges faced by the BWC. Had it succeeded, it would have been another "giant leap" for humankind. When compared to what such a package would have meant when viewed individually, the myriad of small accomplishments achieved since (some of which are described in this book) fade into relative obscurity. This does not mean, however, that those achievements are not significant. The Chinese philosopher Lao-tzu is often quoted as saying "a journey of a thousand miles begins with a single step". These "small steps", when viewed together can become more than the sum of their parts and describe a journey that can take us to surprising destinations. For example, the Sixth Review Conference heard that:

> When the last Intersessional Process started, there was some scepticism about its prospects. Contrary to these forebodings, however, states parties gained considerably from it. … [S]tates parties benefited from a most useful exchange of information and experiences on issues relevant to the effective implementation of the convention. The knowledge creation and its dissemination, which characterized the exchanges, were enriched by the participation in the process of relevant international organizations and national public-health stakeholders.[3]

This book highlights some of the successes of the Second Intersessional Process. For example, Chapters 4 through 7 include details of the many common understandings reached during the annual Meetings of States Parties. The BWC has also become successful enabling work in other forums, and the importance of the role played by the BWC is often lost. For example, Chapter 19 describes how BWC meetings have fostered efforts amongst the various international scientific unions.

It is not always easy to determine where the successes lie. The distributed nature of recent work under the BWC makes it more difficult to ascertain where progress is being made. This book also helps to bring together some of these separate strands. For example, Chapter 8 discusses how the enhanced networking approach developed under the BWC functions and why it represents a significant evolution for the BWC. Equally, the output of the convention's recent work has also been increasingly intangible. These hard-to-pin-down contributions have generated a momentum for the BWC that will hopefully enable it to continue to innovate in how it addresses the security challenges posed by modern biology.

Working across sectors

The 2007–2010 BWC Intersessional Process has seen states recognize that the security issues related to the convention are also connected to problems addressed by other sectors. As Ambassador Georgi Avramchev notes in Chapter 9, it represents:

> a new approach, one that incorporates the efforts of a broader community and not only those of the defence and security sectors. The BWC now also actively pursues partnerships with the public health, agriculture, law enforcement and education sectors, as well as the international scientific community and commercial industry. If

> the potential problem lies in many hands, runs the logic, so must the solution.

As a result, this book contains chapters that look at some of these overlaps and includes contributions from these partners. Chapter 25 looks at the interface between the public-health and security sectors. Chapter 26 examines a similar overlap between security and animal health. Chapter 27 is a contribution from international law enforcement, and Chapter 31 explores some of the developments that underpin a contemporary law enforcement approach to dealing with biological weapons incidents. Chapters 21 and 22 are written by those involved with developing and delivering educational courses on the BWC and biosecurity. Chapter 20 provides the views of one of the major scientific unions.

From states to stakeholders

The BWC has also improved how it engages with different types of stakeholders. We have already heard that the convention is no longer the sole preserve of hardcore security specialists. The boundaries between national delegates and other participants have begun to blur. Contributions to recent meetings (and this book) come from those who work for their governments—such as Chapter 11, written by a member of the French Ministry of Defence; Chapter 13, written by a member of the Public Health Agency of Canada; and Chapter 15, which is written by a member of the Japanese Ministry of Foreign Affairs. They also come from international civil servants (such as this one or Chapter 26, with the contribution from the World Organisation for Animal Health). There are also contributions from practising scientists (Chapter 18), lawyers (Chapter 3) and academics (Chapter 21).

The chapters also describe some interesting, new relationships between governments and those they govern. For example, Chapters 17 and 18 discuss the relationship between those that practice and those that oversee science in Australia and the Netherlands respectively.

Such engagement has not been confined to national agencies or areas of expertise. It has also been geographic. The manner in which topics have been framed in recent BWC meetings seems to have been of more interest to experts from developing countries. For example, Chapter 12 discusses biosafety and biosecurity in Pakistan and Chapter 29 details national

arrangements for dealing with disease in Kenya. There seems to have been a much greater geographic buy-in to the approach adopted by the recent work programme of the BWC. There was a group of around 30 states parties that would regularly attend negotiations during the 1990s, whilst the 2007 through 2010 meetings all had around 100 states participate. As Ambassador Pedro Oyarce notes in Chapter 24:

> We heard authoritative and deeply informative perspectives from developed and developing countries, from international and regional organizations, and from health, agricultural and security experts. In my opinion it would be essential to continue providing assistance for a broad participation of experts from different regions, particularly from the developing and least developed countries. This inclusiveness is a key element to the promotion and implementation of the convention, and important for its universalization.

Working with what we've got

The nature of the global economy changed considerably during the course of the 2007–2010 Intersessional Process. Resources were considerably scarcer at its conclusion than they had been at its start. Everyone, whether they are in the public or private sector, is being asked to do more with less. The BWC is no exception.

Given its broader political history, even before recent financial upheavals, the BWC has had to focus efforts on getting the most out of those resources at its disposal. The entire Intersessional Process itself was born from a need to make the most out of a minimal set of agreements. The BWC, as has been pointed out, is not supported by its own international organization, staffed with hundreds of international civil servants with different experience, skill sets and resources to support efforts to prevent the acquisition and use of biological weapons. Rather it has been necessary to take advantage of capacity where it exists in the international community in a much more organic manner. As Ambassador Masood Khan notes in the next chapter, this has required BWC states parties to begin "to develop the necessary network of collaboration and coordination, a network that must weave international, regional and domestic strands into a flexible and resilient fabric of oversight and prevention".

Such an approach is not without its own challenges. This book also looks at some of the shortcomings of trying to work through networks and with

such a variety of different stakeholders. For example, Chapter 14 includes a discussion of the challenges of strengthening biosafety and biosecurity in the developing world, and Chapter 28 highlights some of the possible hurdles of developing a coordinated, international response to the alleged use of a biological weapon.

By providing details of both successes and challenges, it is hoped that the reader is left with an impression of just how much remains to be done, how many different views, opinions and approaches there are as to the best way forward, but also a sense that current initiatives are building a momentum of their own and harnessing a broader community to strengthen the BWC in innovative ways.

COMPREHENSIVE IMPLEMENTATION

By pulling together these four themes (small steps and giant leaps, working across sectors, from states to stakeholders, as well as working with what we have got), this book provides a narrative of the evolution of how states parties have viewed the implementation of this convention. In its early years it seemed that states adopted a minimalist approach. The text of the convention itself contains few details of what states need to do to implement it. According to Article IV of the BWC:

> Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

There was no additional guidance as to what these measures should include, what they might look like, how they should work in practice or where any assistance might be found to help create and run them.

By the Sixth Review Conference, in 2006, a series of additional understandings had been reached at successive Review Conferences. This provided a limited amount of additional information about some of the areas in which states might need to take action. For example, with regards to outreach to the scientific community, the Second Review Conference

noted the importance of the "inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol".[4] There was still no guidance as to how states were supposed to accomplish this, when or details as to what should be included. Such efforts seem to be largely ancillary to the legislative approach. In 2006 the phrase "national implementation" was still in common usage as a shorthand way to refer to the legislative and regulatory measures "designed effectively to guarantee compliance with the provisions of the Convention within the territory under the jurisdiction or control of a State Party".[5]

As we approach the Seventh Review Conference there seems to be a growing recognition that states need to engage in a much broader range of activities if they are to prohibit and prevent the acquisition and use of biological weapons. These activities require a much larger toolset, encompassing laws, regulations, administrative measures as well as education and outreach. States need to have a better idea of what is being done with the life sciences within their territory, where and by whom. They need robust regimes to make sure that such activities are safe and secure. They need to deal with different agencies, sectors and stakeholders. States must also find ways to work together more effectively at the bilateral, regional and multilateral levels. It should be no surprise if these areas sound familiar. They are closely related to the areas addressed during the 2007–2010 Intersessional Process. By exploring those areas and identifying common understandings, states parties have begun the process of putting in place exactly what they need to develop robust national regimes: details of issues they need to address (Chapter 16 on a sub-state biological weapons programmes in Japan); information on which measures can be of use (Chapter 10 on risk governance); practical examples of how measures work (Chapters 12 and 13 on the national biosafety and biosecurity arrangements in Pakistan and Canada respectively); and sources of expertise, assistance and partnership (Chapter 30 on regional infectious disease surveillance). These resources have flowed from the 2007–2010 BWC Intersessional Process; many highlights of which have been gathered together in this book. This is the story of this Intersessional Process and that in turn is the story of the comprehensive implementation of the BWC.

SECTION A

IMPLEMENTING THE BWC

CHAPTER 2

THE SECOND INTERSESSIONAL PROCESS

Masood Khan

The Biological Weapons Convention (BWC) is a simple instrument, only a few pages long. Its prohibitions are clear, succinct, categorical and definitive, but it is an instrument of principle rather than procedure. It contains no provision for monitoring or verification of compliance, no provision for an implementing organization, no details of how alleged breaches should be investigated, and no organized means of helping states parties meet their obligations. Many considered this a serious shortcoming. For much of the history of the BWC, states parties and others have fretted about the effectiveness of the convention as a practical barrier against the development of biological weapons.

There have been efforts to put some of these mechanisms in place. Negotiations had begun on a protocol to strengthen the BWC, but after many years of work the effort collapsed in disagreement and recrimination in 2001. Much has been said and written about the reasons for this failure. Opinions were sharply divided, but what was beyond doubt was that the future of the BWC as an effective regime was threatened by the bitterness and rancour of the dispute. Following the dramatic suspension of the Fifth Review Conference, in 2001, it seemed possible that multilateral efforts against biological weapons might come to a permanent halt.

Yet this did not happen. Thanks to the resourcefulness and determination of the states parties, the BWC has embarked on a new course: a course that is different from that charted by other regimes to address weapons of mass destruction, but one that is arguably better suited to the unique challenges posed by biological weapons in today's world.

THE FIRST INTERSESSIONAL PROCESS

First came a period of damage control and resuscitation. At the resumed session of the Fifth Review Conference, in 2002, states parties succeeded in putting their differences to one side in order to establish a work programme for 2003 through 2005, at which they would work on several specific topics related to better implementation of the convention. There would be no attempt to negotiate or agree on binding measures or even recommendations. Expectations were correspondingly low. And yet to the surprise of many, the process was a success. Experts from all around the world gathered to share experiences and ideas on how to deal with the threat posed by biological weapons. Officials from health, science and agriculture ministries made connections with their counterparts in defence, justice, foreign affairs and security agencies. In the period after the terrorist atrocities of September 2001, there was great interest in cooperating against the possibility of bioterrorism, and this gave a further boost to the project.

Just as important, the expert meetings provided an opportunity for the world's scientific community and medical professionals to become directly engaged in developing a response to a threat that, in a sense, had become too widespread and all-pervasive for governments to tackle alone. The extraordinary advances achieved in biotechnology meant that biological weapons were—in theory—within reach of the smallest laboratory and most modest budget. No government and international organization could hope to monitor effectively the tens of thousands of small biotechnology facilities in operation worldwide. Clearly this was a problem that needed a collective, multifaceted and multidimensional approach. The work programme of 2003 through 2005 showed that such an approach could work, and started to develop the necessary network of collaboration and coordination, a network that must weave international, regional and domestic strands into a flexible and resilient fabric of oversight and prevention.

THE SIXTH REVIEW CONFERENCE

The Sixth Review Conference, in 2006, over which it was my honour to preside, built on the good results of the Intersessional Process and the confidence it had engendered among states parties. My goal as President

of the Conference was to transcend the divisions of the past, and set the BWC on its new course. This was a challenge, certainly, but one to which states parties were ready to rise. The constructive, practical and realistic manner in which all states parties approached their preparations for the Review Conference, while maintaining their long-standing goals and positions of principle, was a tribute to their wisdom, and testimony to the great potential of the multilateral enterprise. It was a long and difficult Review Conference, but ultimately a successful one.

The Review Conference agreed on a final declaration embodying a common vision for the convention and its implementation, ending a 10-year gap and resolving many of the issues that had so divided states parties. This in itself was a fundamental step forward that opened the way for improved collective action against the threat of biological weapons. The Review Conference also examined many practical measures and, among others, agreed on:

- the Implementation Support Unit for the BWC, addressing a long-standing need for institutional support for the efforts of states parties in implementing both the convention itself and the decisions of the Review Conferences;
- specific measures to obtain universal adherence to the convention;
- an update of the mechanism for confidence-building measures, and foreshadowing a more thorough review in 2011;
- states parties nominating a national point of contact to better coordinate various aspects of national implementation and universalization; and
- various measures to improve national implementation, including Article X of the convention, which deals with the peaceful uses of biological science and technology.

CREATION OF THE SECOND INTERSESSIONAL PROCESS

The Sixth Review Conference also established a detailed new intersessional work programme to help ensure effective implementation of the convention until the Seventh Review Conference, in 2011. Once again the BWC was to hold meetings to discuss and promote common understanding and effective action on a range of implementation issues. It

was also similar to its predecessor in that each year's work would include two meetings—one at the expert level and one among states parties. The duration of the Meeting of Experts was reduced from two weeks to one, but the Meeting of States Parties continued to take place over a single week.

The Sixth Review Conference identified six topics to be addressed over the course of the process:

1. Ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions.
2. Regional and subregional cooperation on implementation of the convention.
3. National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins.
4. Oversight, education, awareness-raising, and adoption and development of codes of conduct with the aim of preventing misuse in the context of advances in bioscience and biotechnology research with the potential of use for purposes prohibited by the convention.
5. With a view to enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, promoting capacity building in the fields of disease surveillance, detection, diagnosis and containment of infectious diseases: (1) for states parties in need of assistance, identifying requirements and requests for capacity enhancement; and (2) from states parties in a position to do so and international organizations, opportunities for providing assistance related to these fields.
6. Provision of assistance and coordination with relevant organizations upon request by any state party in the case of alleged use of biological or toxin weapons, including improving national capabilities for disease surveillance, detection and diagnosis and public-health systems.

The first two topics were scheduled for 2007, the second two for 2008, the fifth topic for 2009 and the last for 2010. The chairmanship of the

meetings would rotate through the regional groups. Each meeting would prepare a factual report of its work and the output of the entire process would be reviewed by the Seventh Review Conference.

CONCLUSION

The BWC is in reasonably good shape as states parties confront the challenges that the regime faces. The outcome of the Sixth Review Conference gave us a solid foundation on which to base our efforts. The Second Intersessional Process has given us a framework through which we can work. We can take some satisfaction from the result, especially in light of the difficulties and divisions we have experienced in the past. But much remains to be done: the success of the Sixth Review Conference was a means to an end, not an end in itself. All states parties needed to continue to work hard to turn words into action, overcome their remaining differences and convert their shared vision into reality. This was the challenge implicit in the Second Intersessional Process. The chapters that follow tell us how states parties fared. It will allow you to judge for yourself whether the BWC, through its work programme from 2007 through 2010, has made a genuine and significant contribution to reducing the risks of biological weapons being developed or used by any actor, anywhere in the world.

CHAPTER 3

NATIONAL IMPLEMENTATION THROUGH AN EFFECTIVE LEGISLATIVE FRAMEWORK

Scott Spence

Once a state has ratified or acceded to the Biological Weapons Convention (BWC), it is bound by the content of the convention and obliged to implement its requirements. In particular, Article IV obliges each state party, in accordance with its constitutional processes, to take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological or toxin weapons in its territory and anywhere under its jurisdiction or control. States parties have agreed that the prohibition of the use of biological weapons—originating in the 1925 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare—also falls under the scope of the BWC. In addition, Article III requires all states parties to refrain from transferring biological and toxin weapons to anyone and from assisting, encouraging or inducing anyone to manufacture or acquire them.

Robust national implementing measures ensure that states can:

- investigate, prosecute and punish any offences, including preparations, associated with biological and toxin weapons activities committed by non-state actors such as terrorists;
- monitor and supervise any activities, including scientific research and transfers, involving especially dangerous biological agents and toxins;
- enhance national security and public health and safety, including disease surveillance;
- signal strongly to potential investors that the state is a safe and responsible location for biotechnology and research; and

- satisfy their obligations, including reporting requirements, under Articles III and IV of the BWC and Security Council resolution 1540.[1]

AGREEMENTS AND UNDERSTANDINGS ON IMPLEMENTATION

In 2006 the Sixth Review Conference took a strong stand on national implementation by reaffirming that the enactment and implementation of necessary national measures under Article IV would strengthen the effectiveness of the convention. In this context, the Conference called upon states parties:

> to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to:
>
> (i) enhance domestic implementation of the Convention and ensure the prohibition and prevention of the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipments and means of delivery as specified in Article I of the Convention;
>
> (ii) apply within their territory, under their jurisdiction or under their control anywhere and apply, if constitutionally possible and in conformity with international law, to actions taken anywhere by natural or legal persons possessing their nationality;
>
> (iii) ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins.[2]

One year later, in 2007, the Meeting of States Parties to the BWC discussed and promoted common understanding and effective action on, inter alia, ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions. The states parties:

> recognised the value of ensuring that national implementation measures:

> (i) penalize and prevent activities that breach any of the prohibitions of the Convention, and are sufficient for prosecuting prohibited activities;
> (ii) prohibit assisting, encouraging or inducing others to breach any of the prohibitions of the Convention;
>
> (iii) are not limited to enacting relevant laws, but also strengthen their national capacities, including the development of necessary human and technological resources;
>
> (iv) include an effective system of export/import controls, adapted to national circumstances and regulatory systems;
>
> (v) avoid hampering the economic and technological development of states parties, or international cooperation in the field of peaceful uses of biological science and technology.[3]

The details of the types of laws and regulations that states parties might consider developing and adopting, in order to effectively implement the BWC, are described in more detail in the next section.

NATIONAL IMPLEMENTING MEASURES

Definitions, crimes and jurisdiction

States should consider including in their penal or counterterrorism legislation a definition for "biological or toxin weapon" that derives from Article I of the convention:

> (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
>
> (2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

States should also include in their penal or counterterrorism legislation a provision to prohibit and prevent certain activities involving biological and toxin weapons including their development, production, acquisition, stockpiling, retention, transfer and use. At the same time, to promote the peaceful use of the life sciences, unlicensed activities involving controlled or "select" biological agents and toxins should be criminalized. More about

this will be discussed below. Preparations to commit any of these offences, for example, attempts, conspiracies, threats and financing should also be criminalized.

In line with the Sixth Review Conference recommendations, states should consider extending the reach of the prohibitions outlined above to all natural and legal persons with that state's nationality who may have committed offences involving biological or toxin weapons outside the state's territories. There should also be measures to facilitate international cooperation on judicial and criminal matters in the event that there is a suspected criminal or terrorist act involving a biological or toxin weapon, and measures to ensure confidentiality of any data and information exchanged.

Biosafety and biosecurity measures

A straightforward way to understand the difference between biosafety and biosecurity is that biosafety measures aim to prevent unintentional exposure to or accidental release of pathogens, while biosecurity measures help prevent unauthorized access, loss, theft, misuse, diversion or intentional release of pathogens. Biosecurity measures, which can be implemented in greater detail through subsidiary legislation such as orders or regulations, fall into three categories: controlled or select agents and toxins lists, licensing and reporting, and national inspections.

Controlled or "select" agent and toxin lists are developed based on the threat to public health and safety and national security. This can be done through a risk-based approach—identifying which particular pathogens and toxins pose the gravest risk of death and disease to the human, animal and plant populations, if used by a terrorist for example. There are also several existing lists, many of which have been developed for export and import control but which could also be applied to internal biosecurity measures, such as licensing and inspections.

Building on these lists, states could consider licensing for individuals and laboratories which are involved in activities with the controlled agents and toxins identified above, including their development, production and use. Regulations could then cover the modalities for issuing and revoking licences, specifying prohibited persons and setting fees, among others. Additional biosecurity measures could include:

- national inspections of laboratories and other facilities where controlled agents or toxins may be found;
- personnel background checks and physically secure labs (within and without);
- biosafety and biosecurity training for personnel;
- notification of loss or theft of any controlled agents or toxins;
- comprehensive record-keeping in laboratories and facilities where controlled agents or toxins are handled;
- internal and international transfer controls through permits;
- robust customs and border controls to identify dual-use biological goods, as well as standard operating procedures for documentation checks, a requirement for end-use certificates, and the provision of detection equipment to customs and other border control officials; and
- provisions requiring secure transportation, including approved carriers, secure containers and packaging, labelling and shipment tracking.

Enforcement

The legislative measures discussed may not be as effective as they could be in the absence of a national authority or other enforcement agency. On this matter the Sixth Review Conference encouraged "States Parties to designate a national focal point for coordinating national implementation of the Convention and communicating with other States Parties and relevant international organizations".[4] Such a focal point could also serve as a national authority to coordinate the implementation of the BWC through adoption and enforcement of national laws and regulations.

A state may wish to consider a national authority with the following representatives (or their equivalents), taking into account national considerations and circumstances:

- prime minister or head of government office;
- ministries of foreign affairs, justice, industry, environment, health, agriculture, interior, and transport;
- office of the attorney-general;

- national forensic science laboratory;
- customs and port authorities; and
- national chamber of commerce or biological industry association.

Some states have, for example, assigned primary responsibilities to the national health authority for licensing laboratories; to the trade and industry ministry for authorising imports and exports of dual-use items; or to the foreign ministry, which may already be liaising with the Implementation Support Unit (ISU) or be involved in Geneva-based BWC meetings and conferences, and therefore familiar with the convention. Moreover, some states have decided to combine their BWC and Chemical Weapons Convention (CWC) focal points into one governmental entity as a matter of efficiency and effectiveness, and have added responsibilities under the BWC to those of their existing CWC national authority. In some cases a national authority has been assigned responsibility for a state's obligations under the biological, chemical and nuclear weapons conventions. A national authority's function could include:

- acting as a national point of contact for the ISU, and issuing full contact details;
- providing data and information relevant to the fulfilment of its international obligations to other states parties and international organizations, including gathering any necessary information to prepare confidence-building measure returns for submission to the ISU;
- sharing experiences and extending assistance to other states pertaining to the implementation of the BWC;
- developing and promulgating lists of controlled agents and toxins and controlled equipment and technology;
- processing licences for activities involving controlled agents and toxins;
- issuing and monitoring compliance with permits for internal and international transfers of controlled agents and toxins and controlled equipment and technology;
- creating and maintaining a national system to respond to biological incidents;

- establishing a national system to monitor and verify activities in authorized facilities;
- proposing and supporting the adoption of legislative and other administrative or regulatory measures to implement the BWC;
- supervising and monitoring the enforcement of legislation and regulations;
- advising the prime minister or head of government on any BWC-related issues;
- reporting to the parliament or national assembly on its activities;
- coordinating and assisting with any of the tasks above attributed to any other government bodies; and
- conducting or facilitating awareness-raising, education, outreach and training vis-à-vis the BWC, biosafety and biosecurity, national implementing legislation and other measures, and codes of conduct for scientists.

In addition to a national authority, a state might consider establishing a system to coordinate and manage the response to natural or intentional outbreaks of disease and investigations of bioterrorism incidents, such as the Verification Research, Training and Information Centre (VERTIC) Biological Emergency Response and Investigation Support System (BERISS). This operational body could include the following representatives, or their equivalents:

- a liaison from the national authority or national focal point for national implementation of the BWC, as well as representatives from the ministries of health, food and drugs, agriculture, and environment;
- an emergency medicine practitioner;
- a law enforcement officer trained to respond to biological emergencies;
- representatives from customs and the ports authorities;
- an epidemiologist;
- a veterinary scientist;
- a media relations specialist; and

- specialists in bacterial, prion, rickettsial, toxicological and viral diseases.

Because BERISS would be operational, its duties would differ substantially from those of the national authority described above, and could include:

- managing and guiding the national and local response to biological emergencies;
- establishing public-health and agricultural surveillance and reporting systems in coordination with other government agencies;
- ensuring the effectiveness of a public emergency announcement system;
- ensuring the proper training and equipping of law enforcement officers, emergency and first responders, and hospitals in responding to biological emergencies;
- creating threat-based medical and public-health detection strategies to detect and determine outbreaks associated with biological agents and toxins;
- receiving and reviewing public-health information and classified biological threat intelligence;
- collecting, maintaining and presenting evidence needed for reviewing forensic epidemiological investigations and for prosecutions;
- transmitting data and information regarding biological emergencies and incidents to the national authority; and
- undertaking other activities regarding preparation for and response to emergencies involving biological agents and toxins, including cooperation with law enforcement officers.

STATUS OF IMPLEMENTATION AND CHALLENGES

Table 3.1 gives a good overview of the status of implementation of the BWC around the world and is the result of ongoing VERTIC analysis of states' legislative frameworks to prevent the misuse of biological agents and toxins. The results underline that there is significant room for improved

national implementation of the BWC, as recognized by the Sixth Review Conference.

Table 3.1 The status of BWC implementation

Measures	No. states parties with measure
Definitions	
Biological weapon	9
Crimes	
Develop biological weapons and penalties	21
Manufacture/produce biological weapons and penalties	37
Acquire biological weapons and penalties	31
Stockpile/store biological weapons and penalties	25
Possess/retain biological weapons and penalties	31
Transfer biological weapons and penalties	34
Use biological weapons and penalties	33
Engage in activities involving dangerous biological agents or toxins without authorization/in violation of the conditions of an authorization and penalties	26
Transfer dangerous biological agents or toxins without authorization/to unauthorized persons and penalties	40
Control lists	
Control lists for dangerous biological agents and toxins	27
Control lists for dual-use biological equipment and related technology	18
Preventative measures	
Measures to account for production	9
Measures to account for use	11
Measures to account for storage	7
Measures to account for transport	12
Measures to secure production	7

Measures	No. states parties with measure
Measures to secure use	9
Measures to secure storage	12
Measures to secure transport	21
Regulations for physical protection of facilities which produce, use or store dangerous biological agents or toxins and related penalties	6
Regulations for physical protection of dangerous biological agents and toxins and related penalties	6
Authorization of activities involving dangerous biological agents or toxins	33
National licensing authority	26
Regulations for genetic engineering work	34
Transfer controls	
Authorization for exports and imports of dangerous biological agents and toxins	59
Export/import control authority	39
End-user controls for dangerous biological agents and toxins	22
Transit control over dangerous biological agents and toxins	24
Trans-shipment control over dangerous biological agents and toxins	6
Re-export control over dangerous biological agents and toxins	17
Export control over dangerous biological agents and toxins	39
Import control over dangerous biological agents and toxins	45

Notes: As of 1 November 2010. The total number of states parties is 109.

One of the main challenges to effectively regulating biological materials is the absence of an intergovernmental organization, such as the Organization for the Prohibition of Chemical Weapons or the International Atomic Energy Agency, to oversee and support comprehensive, centralized implementation of the BWC, including legislative assistance. These organizations' legal offices, for example, have prepared guidance materials and carried out legal drafting workshops and follow-up activities for governments around the world.

Implementation of the convention is not only complicated by an institutional deficit, it also faces:

- the lack of universality in the BWC membership and a perception in non-states parties that they do not have to implement effective controls on biological materials ("We don't have biological weapons");
- a lack of awareness of the BWC and Security Council resolution 1540 and their requirements and obligations, as well as a lack of political will to implement these instruments at the national level;
- limited or no technical, human or financial capacity for drafting implementing laws and regulations, training relevant officials, or enforcement;
- difficulty maintaining momentum in the implementation process due to government official turnover, elections and changes in government, or internal or external conflicts; and
- competing legislative, parliamentary, budgetary or economic priorities.

Despite these challenges, there are efforts underway by civil society actors to promote and strengthen the BWC. The VERTIC National Implementation Measures (NIM) Programme is one of these.

COOPERATION FOR ROBUST LEGISLATIVE FRAMEWORKS

VERTIC has developed the NIM Programme largely—but not completely—focused on the BWC. The NIM Programme was developed to assist states in understanding what measures are required at the national level to comply with the prohibitions in a range of nuclear, biological and chemical weapons conventions and Security Council resolutions and how

to implement them. With funding from the governments of Canada, the United Kingdom and the United States, the programme has a staff of four, as well as a consultant assisting with the Middle East and North Africa portfolio.

The programme has four objectives. First, the NIM team is in the process of preparing comprehensive analyses of existing legislation in countries around the world for the implementation of the BWC and related provisions of Security Council resolution 1540. As of 1 November 2010, the team had completed surveys for 109 states. Some results of this analysis are presented in Table 3.1, which underlines the enormous amount of drafting and adoption of laws and regulations that remains to be done.

Second, based on the gap analyses, VERTIC provides direct legislative drafting assistance, or other forms of help, including remote reviews of draft legislation, legal advice and information exchanges to governments. VERTIC is fully funded, so governments are not charged for these services. VERTIC has provided direct assistance to over 20 states since 2008 and is responding to a sharp increase in interest.

Third, in order to carry out this cooperation and assistance, VERTIC has developed an "Implementation Kit"—the first of its kind for the BWC. It consists of fact sheets on the convention and the establishment of national authorities, a sample act for national implementation of the convention, regulatory guidelines to further implement the convention, and sample BWC accession and ratification instruments and guidance on joining the convention. All of this material is available in several languages on the VERTIC NIM Programme website. The sample act and regulatory guidelines devote considerable space to biosecurity, including licensing, inspections, enforcement mechanisms and transfers controls for particularly dangerous biological agents and toxins and dual-use biological equipment.

Finally, the NIM Programme team also spends a considerable amount of time engaging in outreach—this includes staff participation in symposiums, conferences and workshops, and, of course, participation in the BWC Meetings of Experts and States Parties. VERTIC also promotes universalization of the BWC and the establishment of national authorities.

CONCLUSION

National implementation of the BWC is one of the most important ways by which proliferation of biological agents and toxins for the purpose of killing or harming humans, plants or animals can be prevented. However, the benefits of implementation extend beyond this to facilitating robust mechanisms for disease surveillance, responding to natural or intentional disease outbreaks, and international cooperation. International security is only as strong as the weakest link in the chain and legislative frameworks, in the context of the BWC, have a number of gaps for several reasons, including lack of capacity and competing government priorities.

Nonetheless, the Sixth Review Conference and the Meeting of the States Parties in 2007 called upon governments to strengthen their legislative frameworks in all areas, including penal provisions, extraterritorial jurisdiction, export and import control and biosecurity measures. This process has recently become more straightforward with dedicated support to states to carry out this work through organizations such as VERTIC, which has developed a programme of legislative cooperation and a range of guidance materials in several languages.

CHAPTER 4

THE WORK OF THE BWC IN 2007

Implementation Support Unit (ISU)[1]

In 2007 the Biological Weapons Convention (BWC), cornerstone of international efforts to prevent the malign use of the life sciences, continued to build steadily upon its recent successes. The convention's annual meetings from 2003 through 2005 proved to be an innovative and productive process, which refocused international efforts on the evolving biological weapons threat. The Sixth Review Conference, in 2006, was praised for its forward thinking and comprehensive efforts. In accordance with the decisions and recommendations adopted by consensus at the Review Conference in 2007, the BWC embarked on a new cycle of meetings leading up to the Seventh Review Conference, in 2011.

International concerns over biological weapons, and in particular the risks of bioterrorism, have reinvigorated efforts under the BWC. The annual Meetings of Experts and States Parties provide opportunities for states parties to meet, discuss and promote common understanding and effective action on issues critical to improving the implementation of the convention. This new relevance has led to increasing levels of participation in BWC activities.

In contrast to the difficulties and divisions that surrounded the end of the Ad Hoc Group negotiations and the Fifth Review Conference, in 2001, the annual meetings have been largely non-controversial and collegial in nature, enabling the international community to draw, as necessary, from expertise held by states and international organizations as well as by the non-governmental and private sectors. The meetings have proved successful in bridging gaps between different viewpoints and in highlighting existing common ground. During years characterized by setbacks and limited progress in some other disarmament and non-proliferation settings, the BWC has made steady progress, culminating in the broad and extensive agreements reached at the Sixth Review Conference.

The 2007–2010 Intersessional Process continued where the earlier meetings left off. It covered a wide variety of topics relevant to both preventing malign use and enhancing the peaceful use of the life sciences. In 2007 states parties considered two specific topics as mandated by the Review Conference:

1. Ways and means to enhance national implementation, including enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions.
2. Regional and sub-regional cooperation on implementation of the convention.

In addition to the specific issues for 2007, states parties also addressed a number of recurring themes, which they committed themselves to revisit every year in the lead up to the next Review Conference. States parties reviewed progress made in persuading states outside the convention to join—a priority identified in 2006. States parties also reviewed the activities of the ISU, established by the Sixth Review Conference and housed in the Geneva Branch of the United Nations Office for Disarmament Affairs (UNODA).

MEETING OF EXPERTS (20–24 AUGUST 2007)

Ninety-three states parties—almost two-thirds of the membership of the BWC—participated in the Meeting of Experts, along with five signatory states and one state outside the regime (which was granted observer status). Delegations were made up of a mix of experts in:

- biodefence;
- biological and life sciences;
- biosafety and biosecurity;
- diplomacy;
- economics and finance;
- emergency response;
- environment;

- international relations;
- military issues;
- non-proliferation and disarmament; and
- public, animal and plant health.

Delegations from states were joined by international and regional organizations, including those covering international humanitarian law, law enforcement and unconventional weapons.[2] Two representatives of the United Nations[3] and 10 non-governmental organizations (NGOs) and research institutes also attended the meeting. As a result, the Meeting of Experts was able to draw upon expertise from both public and private sectors, as well as from independent, national, regional and international perspectives. The benefits of this broad base of expertise were evident both in the discussions that took place during both formal and informal sessions and through events on the margins of the meeting.

Under the chairmanship of Ambassador Masood Khan of Pakistan, the substantive work of the meeting began with two formal sessions offering opportunities for states and international organizations to make observations and comments across the full breadth of the international prohibition of biological weapons. Fourteen states, many on behalf of broader groups, made statements, as did a number of international organizations.[4] NGOs, research institutes and the private sector also had an opportunity to address delegations in an informal session on the opening day. Seven organizations took advantage of this opportunity.

Five working sessions were held over subsequent days. These were tailored to the specific topics under consideration. Contributions to the discussions were numerous: a total of 42 statements and presentations were made by states. Five international organizations briefed participants. This sparked considerable discussion and interaction from participants. Two lunchtime events hosted by the United Nations and NGOs offered opportunities to explore issues in greater depth and in an informal setting.

Delegations were also able to draw upon a variety of other resources. Twenty-two working papers were circulated during the meeting. The ISU drafted a series of background papers on previous agreements, understandings and proposals, as well as international and regional initiatives, to enhance national implementation of the convention. The

ISU also introduced its National Implementation Database, an online tool listing relevant measures currently in force, or under development, around the world. During the course of the meeting, the Chairman compiled a list of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the discussions and resources available. As in previous years, this document was annexed to the report of the meeting.

The final day of the meeting was devoted to reviewing progress on universalization of the BWC, as well as summarizing what had taken place throughout the week in the report of the meeting.[5] The function of the report of the Meeting of Experts was to feed into the Meeting of States Parties the detailed technical information derived from the expansive presentations, statements, papers and other resources. The Meeting of States Parties was then to reconfigure this information into the framework of the convention, draw from it common understandings, and thereby promote effective action by states parties—both individually and collectively. In his concluding remarks, following the adoption of the report, the Chairman highlighted that the Meeting of Experts had developed synergies both within and across delegations:

> Experts will go back to their capitals and engage with their governments with a broader perspective, new ideas and greater confidence. This will help move the BWC higher on national agendas, and will give a renewed impetus to national implementation and regional cooperation activities in many states parties.[6]

MEETING OF STATES PARTIES (10–14 DECEMBER 2007)

Present at the December meeting were representatives from 95 states parties, six signatory states, two states not currently party, two representatives of the United Nations, six international organizations, two regional organizations, as well as 20 NGOs, research institutes and industry representatives.

The heads of three international organizations participated in the meeting: the Director-General of the World Organisation for Animal Health, Bernard Vallat; the Secretary General of INTERPOL, Ronald Noble; and the Director-General of the OPCW, Rogelio Pfirter. The Food and Agriculture Organization of the United Nations and the World

Health Organization participated at the Assistant Director-General level. Many of the delegations from states parties included senior figures from non-proliferation, disarmament and multilateral departments of foreign ministries.

Following the success of the Meeting of Experts in August, the Chairman attempted to bring together an even wider array of stakeholders for the Meeting of States Parties, introducing a theme of "from adjacency to synergy". One sector he identified as being not sufficiently engaged was that of commercial industry. To remedy this, he invited representatives from the biotechnology industry, biosafety and security professional societies, synthetic biology, trade organizations and the policymaking community to engage in the meeting via an interactive panel discussion. This discussion provided an opportunity to showcase industry views, allowed the Chairman to highlight issues of overlap between industry and the convention, and prompted an active debate between panel members and delegations from states parties.

A second panel discussion was held to enhance interaction between states and experts from NGOs. Participants on this second panel included academics and researchers on international security, national implementation, the biological sciences, the impact of the sciences on society, and public policy. The panel provided additional opportunities for delegations to share views and opinions and draw directly from an expanded set of experience and backgrounds. In addition to the panel discussions, informal lunchtime side events hosted by states and NGOs continued to play an important role in fostering interaction.

This combination of interest, high-level participation, interaction and expertise provided a good basis for reaching common understandings and promoting effective national action. The technical information from the Meeting of Experts was developed into a short synthesis document.[7] This document provided a tool for states parties to find common ground. At the end of the meeting the Chairman recalled:

> I said at the beginning of our meeting that our yardstick for measuring success should be: "will this report be a useful, practical tool for governments wanting to improve their implementation of the BWC?" I think that it will.[8]

The substantive sections of the report of the 2007 Meeting of States Parties significantly expanded upon previously articulated common understandings on both the topics.[9] A summary of the understanding identified can be found in Annex I. States parties outlined the aims of national implementation, which were to:

- adopt measures to translate international obligations into domestic action;
- tailor national measures to respective circumstances;
- manage, coordinate, enforce and regularly review national measures; and
- facilitate economic and technological development and international cooperation.

The report detailed common understandings on how to go about realizing these aims, including:

- six understandings on desirable national mechanisms;
- five components of national implementation measures;
- five priorities for enforcement capacity; and
- four important ongoing activities.

The report further recorded that the aim of regional and subregional cooperation was to:

- complement and reinforce national measures;
- promote international cooperation; and
- exchange experiences and best practices on implementing the BWC.

To realize these aims, states parties reached a number of common understandings:

- five approaches to regional and sub-regional cooperation;
- three understandings on the provision of resources; and
- three modalities for sharing information.

CHAPTER 5

THE WORK OF THE BWC IN 2008

Implementation Support Unit (ISU)[1]

In 2008 the Biological Weapons Convention (BWC) continued to assist the international community in focusing on ensuring the life sciences are used solely for our collective benefit. By the end of the year the BWC was halfway through the Intersessional Process of annual meetings to discuss and promote common understanding and effective action on issues critical to improving the implementation of the convention.

The format of the annual meetings—comprising sessions at both the expert and state party level—provided an opportunity for delegations to interact, draw upon the best international expertise, develop ties with stakeholder communities, and work together and individually to realize the global ban on the misuse of biology for hostile purposes.

The meetings in 2008 examined two specific topics of the work of the BWC:

1. National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins.
2. Oversight, education, awareness-raising, and adoption and development of codes of conduct with the aim of preventing misuse in the context of advances in bioscience and biotechnology research with the potential of use for purposes prohibited by the convention.

MEETING OF EXPERTS (18–22 AUGUST 2008)

The Meeting of Experts, held in August, provided an opportunity for a wide range of experts to share and discuss a large amount of information

on these topics. This information was then processed by the Chairman and the ISU into a more usable format prior to the Meeting of States Parties in December, which was tasked with developing common understandings on how these issues could be implemented, paving the way for effective action.

In total 103 states took part in the 2008 Meeting of Experts—the second highest attendance ever for a BWC meeting. This total included 96 states parties, four signatory states and three states from outside the regime (which were granted observer status). The national delegations were joined by four representatives of the United Nations[2] and seven specialized agencies or other international organizations,[3] including those dealing with cooperation and development, disarmament and non-proliferation, education and social issues, the environment, international humanitarian law, public and animal health, technology, as well as unconventional weapons. At the invitation of the Chairman and in recognition of the special nature of the topics under consideration, 13 scientific, professional, academic and industry bodies participated in the meeting as Guests of the Meeting of Experts.[4] Fifteen other non-governmental organizations (NGOs) and research institutes attended the meeting. In total almost 500 individuals, including some 180 technical experts, gathered in Geneva to consider the two assigned topics. Such a large number and diverse range of participants allowed the Meeting of Experts to draw upon expertise from both public and private sectors, as well as from independent, national, regional and international perspectives. The benefits of having such a broad base of expertise were evident throughout the formal and informal sessions, as well as during events held on the margins of the meeting.

Under the chairmanship of Ambassador Georgi Avramchev of the former Yugoslav Republic of Macedonia, the substantive work of the meeting began with two formal sessions offering opportunities for states and international organizations to make general observations and introductory comments. Twenty states, many on behalf of broader groups, made statements, as did one international organization.[5] NGOs, research institutes and the private sector also had an opportunity to address delegations on the opening day. Eleven organizations took advantage of this opportunity.

Seven working sessions, covering both topics, were held over subsequent days. For the first time at a BWC meeting, all working sessions were held in public and all the participants were able to take part in each session. Thirty-

five states parties, one observer state, seven international organizations and six guests of the meeting made presentations and statements on biosafety and biosecurity. Twenty-two states parties, two international organizations and two guests of the meeting made presentations and statements on oversight, education, awareness-raising and codes of conduct.

In addition to the statements and presentation that took place during the working sessions, the Meeting of Experts also held three panel discussions. Each panel, composed of international experts invited by the Chairman, focused on a specific aspect covered by the meeting. The first panel took place on 19 August and focused on the role of industry and the private sector in biosafety and biosecurity. The second panel took place on 20 August and looked at risk assessment, management and communication concepts and techniques. The third panel took place on 21 August and covered aspects of the oversight of science and engagement of stakeholders. Panel members each made some opening remarks before engaging in a structured discussion with the Chairman. Following this, the discussion was opened to the floor, allowing all delegations to question the panel members, make comments and contribute to the debate.

There was also a full timetable of side events held on the margins of the meetings. The Chairman organized two poster sessions—one for each topic—in order to maximize opportunities for experts to meet their counterparts and network. Both the poster session on biosafety and biosecurity (sponsored by Canada and held on 19 August) and the poster session on oversight, education, awareness-raising and codes (sponsored by the United Kingdom and held on 21 August) were enthusiastically received by the participants. Both provided additional technical information and allowed participants to process the data at their own speed and interact with the authors of the posters.

Other side events were organized by professional, academic and other NGOs. On 18 August the Geneva Forum held an event entitled “Synthetic Biology: Engineering Biology”. On 19 August a collection of academic technical experts from Germany, the United Kingdom and the United States held an event entitled “Dual-Use at the Cutting Edge: What to do about Oversight”. On 20 August the IBWG held a breakfast meeting on biosafety and biosecurity, and the BioWeapons Prevention Project hosted a lunchtime event to introduce delegations to a cross-section of its network members. On 21 August the IAP and the NAS held a lunchtime event on

the Second International Forum on Biosecurity. The Verification Research, Training and Information Centre hosted a lunch event on 22 August entitled "National Implementation Measures for Effective Biosecurity and Biosafety".

Delegations were also able to draw upon a variety of other resources in their work. Thirty-five working papers were circulated during the meeting. The ISU drafted a series of background papers on "Biosafety and Biosecurity", "Developments in Codes of Conduct Since 2005", "Oversight of Science" and "Education, Outreach and Raising Awareness". The ISU also introduced its Compendiums of National Approaches, an online tool describing how states parties operationalize the legislation and regulations contained in the National Implementation Database (introduced in 2007)[6] as well as the measures developed to translate the obligations of the convention into effective action. During the course of the meeting, the Chairman compiled a list of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the discussions and resources available. As in previous years, this document was annexed to the report of the meeting.

The final session of the meeting was devoted to summarizing its work in a factual report.[7] Delegations also heard an interim progress report from the Chairman on universalization activities. The report was adopted by consensus and the meeting closed as scheduled on 22 August. In his concluding remarks the Chairman highlighted that the Meeting of Experts had covered a great deal of ground and succeeded in identifying key areas of common understanding:

> it was always going to be a challenge to do justice to our two very broad topics in just one week. We could quite easily have devoted one full week to biosafety and biosecurity, and another full week to oversight, education, awareness-raising and codes of conduct. As we have heard, there are many aspects and considerations to both these topics. We have heard many perspectives, from States Parties, from international organizations, from scientific and professional associations, and from NGOs. … Indeed, it is striking that there was very little in the way of disagreement or contradiction.[8]

MEETING OF STATES PARTIES (1–5 DECEMBER 2008)

Following the success of the Meeting of Experts in August, the Chairman attempted to create an environment that would help states parties convert the large amount of information generated into specific common understandings. To this end, the meeting was themed *refinement, structure and focus*. Continued interest in the topics on the table was evident from another impressive turnout. Participating at the December meeting were representatives from 97 states parties, five signatory states, one state not currently party, two representatives of the United Nations,[9] four international organizations,[10] and 17 NGOs, research institutes and industry representatives.

The meeting began with a substantive general debate, which opened with a message of support from Secretary-General Ban Ki-moon delivered by the Director-General of the United Nations Office at Geneva, Sergei Ordzhonikidze. Twenty-four states, many on behalf of larger groups of states, and one international organization then made opening remarks.

The Chairman held one public working session devoted to practical initiatives that embodied the concepts under discussion. The Chairman opened this session by summarizing a meeting of the National Science Advisory Board for Biosecurity he had attended in the United States the previous month. The session also heard presentations from: Det Norske Veritas on a "Laboratory Biorisk Management Standard"; Georgia on "New Challenges to Biosafety and Biosecurity"; the International Association Synthetic Biology on its activities; the United States on its "Biosecurity Engagement Programme"; and the University of California at Berkley on "Grassroots Biosecurity Initiatives".

The Meeting of States Parties also held a working session on the *Report of the Chairman on universalization activities*[11] and the *Report of the Implementation Support Unit*.[12] The remainder of the work of the meeting was conducted in private working sessions.

As with the Meeting of Experts, the Meeting of States Parties was notable for the degree of common outlook and purpose exhibited by delegations across the geographic and political spectrum. Several states noted how successful the meeting had been in terms of both content and process. Iran observed that a clear theme which ran through both topics during

the deliberations was that of balance and of the need for proportional measures, for carefully assessing risks, for balancing security concerns against the need of nurturing research and ensuring the peaceful development of biological science and technology. The United States noted that the meeting stayed above politics and worked for a higher cause.

The Chairman agreed with these sentiments and in his closing remarks asserted:

> we can be satisfied that we are taking the right steps to strengthen the Convention ... . I have been impressed by the strength of common purpose exhibited throughout our work this year. ... One highlight of our work this year has been the degree of involvement of the scientific community. ... [W]e have worked together in a positive and collegial atmosphere to focus on practical measures.[13]

The Meeting of States Parties succeeded in delivering a comprehensive range of common understandings. The report of the meeting[14] significantly expanded upon previously articulated common understandings on both the topics.[15] A summary of the understanding identified can be found in Annex I. The meeting agreed on what the terms biosafety and biosecurity mean in the context of the convention:

> *biosafety* refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and *biosecurity* refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.[16]

Common understandings reached on the first topic established that the aims of dealing with biosafety and biosecurity were to contribute to: preventing the development, acquisition or use of biological and toxin weapons; implementing the convention; and fulfilling other international obligations and agreements (such as the revised International Health Regulations of the WHO and the provisions of Security Council resolution 1540). The report also recorded common understandings on how to go about realizing these aims, including: 10 characteristics that measures should have; seven components of biosafety and biosecurity measures;

seven tools for their implementation; and four types of assistance that are needed.

The report further emphasized the importance of balancing "top-down" government or institutional controls with "bottom-up" oversight by scientific establishments and scientists themselves. To this end:

> States Parties welcomed the important contributions made to their work by the scientific community and academia, including national and international academies of science and professional associations, as well as industry-led initiatives to address recent developments in science and technology, and encouraged greater cooperation between scientific bodies in various States Parties.[17]

States parties described the aims of oversight, education, awareness-raising and codes of conduct, which were to ensure that those working in the biological sciences are: aware of their obligations under the convention and relevant national legislation and guidelines; have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities; and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including bioterrorism. They went on to detail 10 characteristics that oversight frameworks should have; six components for education and awareness-raising; and three next steps for codes of conduct.

CHAPTER 6

THE WORK OF THE BWC IN 2009

Implementation Support Unit (ISU)[1]

In 2009 the Biological Weapons Convention (BWC) continued to develop national capacities to deal with the threat of the life sciences being used as a weapon. Through its meetings, the BWC continues to build a community dedicated to preventing the hostile use of the life sciences and sustained work in areas to ensure that biology is used solely for peaceful purposes.

Through the Intersessional Process the BWC has been working to bridge gaps between different viewpoints. It has brought states parties closer together and fostered a positive working environment, which has yielded practical improvements in national capacity to deal with biological weapons. The BWC must now use the current momentum to cement gains and translate national efforts into international results.

The meetings in 2009 were mandated to:

> With a view to enhancing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes, promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of infectious diseases: (1) for States Parties in need of assistance, identifying requirements and requests for capacity enhancement; and (2) from States Parties in a position to do so, and international organizations, opportunities for providing assistance related to these fields.[2]

MEETING OF EXPERTS (24–28 AUGUST 2009)

In total 103 states took part in the 2009 Meeting of Experts—a similar number present in 2008. This included 96 states parties, four signatory states, and three states from outside the regime (which were granted

observer status). The national delegations were joined by three representatives of the United Nations[3] and six specialized agencies or other international organizations,[4] including those dealing with disarmament and non-proliferation, crime and justice, international humanitarian law, technology, as well as public, animal and plant health. At the invitation of the Chairman and in recognition of the special nature of the topics under consideration, 10 scientific, professional, academic and industry bodies participated in the meeting as Guests of the Meeting of Experts.[5] Sixteen other non-governmental organizations (NGOs) and research institutes attended the meeting. In total almost 500 individuals, including some 190 technical experts, gathered in Geneva. Such a large number and diverse range of participants allowed the Meeting of Experts to draw upon expertise from both public and private sectors, as well as from independent, national, regional and international perspectives. The benefits of having such a broad base of expertise were evident throughout the formal and informal sessions, as well as during events held on the margins of the meeting.

Under the chairmanship of Ambassador Marius Grinius of Canada, the substantive work of the meeting began with a formal session offering opportunities for states to make general observations and introductory comments. Twenty-five states, many on behalf of broader groups, made statements.[6] NGOs, research institutes and the private sector also had an opportunity to address delegations on the opening day. Nine organizations took advantage of this opportunity.

Seven working sessions, covering all aspects of the topic, were held over subsequent days. For the first time at a meeting of the BWC, not only were all working sessions held in public, but they were broadcast live over the Internet. Fifty-one states parties, five international organizations, and nine guests of the meeting made presentations and statements.

In addition to the statements and presentation made during working sessions, the Meeting of Experts also included a poster session in the afternoon on 27 August. Twenty-seven posters were presented at the meeting by a wide array of states, international organizations, guests of the meeting and other NGOs. The posters were enthusiastically received by participants as this session provided additional technical information, enabled everyone to process data at their own speed, and allowed for improved interaction with experts.

The Meeting of Experts also benefited from a full schedule of side events organized by professional, academic and other non-governmental groups as well as states, guests of the meeting and even the ISU. On 24 August, the European Union launched its second Joint Action in support of the BWC, and the ISU held a speed-networking session which helped experts present at the meeting to get to know one and other. On 25 August, a breakfast session held by the European Union introduced a separate Joint Action in support of the biosafety and biosecurity work of the WHO and at lunchtime, the ICLS held an event on regional disease surveillance networks. The lunch event on 26 August saw a collection of states parties hold a panel discussion on national experiences and response to H1N1 influenza. On 27 August, an independent expert, Anupa Gupte, held a breakfast session on implementing ecohealth surveillance and the ISBI held a lunch event on stockpiling and delivery of medical countermeasures. The ISBI held a second event—a breakfast session on the political implications of the possible de novo synthesis of smallpox—on 28 August.

Delegations were also able to draw upon a variety of other resources. Twenty-eight working papers were circulated during the meeting. The ISU drafted a series of background papers[7] and introduced a "Compendium of National Approaches to Disease Surveillance, Detection, Diagnosis, and Containment of Infectious Diseases (Including Efforts to Build Capacity)", which is an online tool describing, on a practical level, how states parties address these issues at the national level. During the course of the meeting, the Chairman compiled a list of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the discussions and resources available. As in previous years, this document was annexed to the report.

The final session of the meeting was devoted to summarizing the work in a report.[8] Delegations also heard remarks by the Chairman on universalization activities. The report was adopted by consensus and the meeting closed as scheduled on 28 August. In his concluding remarks, the Chairman highlighted that the Meeting of Experts had managed to cover a great deal of ground and had laid a firm foundation for both reaching common understandings on dealing with disease and for actually building national capacity:

> We have heard a wide range of perspectives, from a variety of agencies in both developed and developing countries, from international and

> regional organizations, from informal initiatives and networks, from academia and NGOs, and from the private sector. We have heard about existing activities, past projects and future plans. We have heard about resources available, assistance extended, cooperation undertaken, and opportunities waiting. And just as importantly, we have heard about needs and challenges, shortfalls in capacity and resources, and obstacles and difficulties in coordination, cooperation and development.[9]

MEETING OF STATES PARTIES (1–5 DECEMBER 2008)

Following the success of the Meeting of Experts in August, the Chairman was to keen to build on the momentum. He structured his inter-meeting efforts around four themes: sustainability; integration approaches to humans, animals and plants; improving coordination; and addressing specific needs and requirements. The Chairman wrote to states parties in October to encourage them to pursue an "action-oriented product" for 2009 that would be of practical assistance to all states parties and enable them to take effective action in building capacity for dealing with disease. To this end, the meeting was themed "Information for Action".

This approach clearly struck a chord as the Meeting of States Parties enjoyed the highest level of participation of any intersessional meeting to date, and the second highest turn out of any BWC meeting. Participating at the December meeting were representatives from 100 states parties, six signatory states, two states not currently party, three representatives of the United Nations,[10] four international organizations,[11] and fourteen NGOs, research institutes and industry representatives.

The meeting began with a substantive general debate, during which 29 states, many on behalf of larger groups, made opening remarks.[12] The Meeting of States Parties was also addressed by US Under Secretary of State for Arms Control and International Security, Ellen Tauscher, who revealed their new national strategy for addressing biological threats. States parties structured their discussion of building capacity to deal with disease through sessions devoted to: aims; addressing problems, challenges, needs and restrictions; developing mechanisms for building capacity; developing the necessary infrastructure; developing human resources; and developing standard operating procedures (SOPs). The Meeting of States Parties also held a working session on the report of the Chairman on universalization

activities and the report of the ISU. The whole meeting was conducted in public.

Through the report of the meeting,[13] states parties agreed on the value of working together to promote capacity-building to deal with disease and that such efforts would directly support the objectives of the convention. This strengthens considerations of the interface between health and security under the BWC and reinforces the link between measures to deal with biological weapons and natural and accidental disease. This approach is built upon an understanding that there is a spectrum of causes for biological risks and threats (see Chapter 24).

The Meeting of States Parties succeeded in delivering a comprehensive range of common understandings. They can be split roughly into two areas: pillars for building capacity; and cross-cutting themes. A summary of the understanding identified can be found in the Annex. The pillars identified at the meeting includes: eight insights for developing human resources; seven components for effective infrastructure; and five aspects of implementing shared practices and SOPs. Cross-cutting themes included: eight measures for ensuring the sustainability; four ways to help improve integration; four considerations for overcoming challenges; and three mechanisms to enhance coordination.

CHAPTER 7

THE WORK OF THE BWC IN 2010

Ngoc Phuong Huynh[1]

In 2010 the Biological Weapons Convention (BWC) continued to develop national capacities to deal with the threat of the life sciences being used as a weapon, this time with a focus on the international community's response in the case of alleged use of biological weapons. In 2010 the BWC reached the last year of its current Intersessional Process, which runs between the Sixth Review Conference, held in 2006, and the Seventh Review Conference, scheduled for 2011. The BWC is now beginning to look forwards and is using its current momentum to cement its gains and translate national efforts into international results.

The meetings in 2010 were mandated to discuss and promote common understanding and effective action on the:

> Provision of assistance and coordination with relevant organizations upon request by any State Party in the case of alleged use of biological or toxin weapons, including improving national capabilities for disease surveillance, detection and diagnosis and public-health systems.[2]

MEETING OF EXPERTS (23–27 AUGUST 2010)

A total of 95 states took part in the 2010 Meeting of Experts. This included 89 states parties, four signatory states, and two states from outside the regime (which were granted observer status). The national delegations were joined by representatives of the United Nations[3] and eight specialized agencies or other international organizations,[4] including those dealing with disarmament and non-proliferation, crime and justice, law enforcement, international humanitarian law, technology, as well as public, animal and plant health. At the invitation of the Chairman, and in recognition of the special nature of the topics under consideration, two scientific and

academic bodies participated in the meeting as Guests of the Meeting of Experts.[5] Sixteen other non-governmental organizations (NGOs) and research institutes attended the meeting. In total almost 450 individuals, including some 250 technical experts, gathered in Geneva to consider the assigned topic. Such a large number and diverse range of participants allowed the Meeting of Experts to draw upon expertise from independent, national, regional and international perspectives. The benefits of having such a broad base of expertise present were evident throughout the formal and informal sessions, as well as during events held on the margins of the meeting.

Under the chairmanship of Ambassador Pedro Oyarce of Chile, the substantive work of the meeting began with a formal session offering opportunities for states to make general observations and introductory comments. Twenty-five states, some on behalf of broader groups, and one international organization made statements.[6] NGOs and research institutes also had an opportunity to address delegations on the opening day. Eight organizations took advantage of this opportunity.

Six working sessions, covering all aspects of the topic, and an informal discussion panel dedicated to scientific and technological advances relevant to responding to alleged use of biological weapons, were held over subsequent days. As was the case in 2009, not only were all working sessions held in public, they were broadcast live over the Internet. Forty states parties and nine international organizations made presentations and statements. The topic of the meeting was broken down into five sub-topics:

- national efforts for assistance and coordination;
- provision of assistance and coordination with relevant organizations: health aspects;
- provision of assistance and coordination with relevant organizations: security aspects;
- improving national capabilities for disease surveillance, detection and diagnosis and public-health systems; and
- improving national capabilities to conduct criminal enquiries and for security response.

In addition to the statements and presentations made during working sessions, for the third consecutive year the Meeting of Experts also included a poster session, which was held on 24 August. Almost 30 posters were presented by a wide array of states, international organizations, guests of the meeting and NGOs. Once again the posters were enthusiastically received by participants, and the session provided additional technical information, enabled delegates to process data at their own speed, and allowed for improved interaction among experts.

The Meeting of Experts also benefited from a full schedule of side events organized by professional, academic and other non-governmental groups, as well as states, guests of the meeting and the ISU. On 23 August the University of Bradford held a lunch event on preparing for the Seventh Review Conference, and for the second consecutive year the ISU held a speed-networking session which helped experts at the meeting to get to know one another. At the breakfast session on 24 August the WHO held an exercise on the role of the International Health Regulations in the case of possible use of biological agents and toxins, and at lunchtime the University of Exeter and the InterAcademy Panel on International Issues held an event on education and awareness-raising. The breakfast event on 25 August was held by the Geneva Forum to discuss opportunities to enhance the BWC confidence-building measures, while the lunch session was dedicated to a discussion on synthetic biology jointly organized by the Geneva Forum and the ISU. On 26 August the United States held a breakfast session on global efforts to enhance health and law enforcement cooperation, and at lunchtime the International Security and Biopolicy Institute discussed various proposals for the progress of the Seventh Review Conference. On 27 August an independent expert, Anupa Gupte, held a breakfast session on international cooperation mechanisms for scientific, technical and technological matters of BWC implementation.

Delegations were also able to draw upon a variety of other resources. Fifteen working papers were circulated during the meeting, and the ISU drafted a series of background papers.[7]

During the course of the meeting, the Chairman compiled a list of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the discussions and resources available. As in previous years, this document was annexed to the report.

The final session of the meeting was devoted to summarizing the work in a report.8 Delegations also heard remarks by the Chairman on universalization activities. The report was adopted by consensus and the meeting closed as scheduled on 27 August.

> Summing up the discussions, the Chairman said that the Meeting of Experts had produced "a vast array of valuable, compelling material on every aspect of the topic. We have heard authoritative and deeply informative perspectives from developed and developing countries, from international and regional organizations, from health experts, agricultural experts, and security experts". The Chairman added that the task of the States parties was now "to distil the essence of this information, to identify common themes and to draw out the key elements, both in order to answer the fundamental question of how the States parties would respond if a biological weapon were to be used tomorrow, and to take genuinely effective and coordinated action to provide assistance and to build national capabilities for responding to disease outbreaks".[9]

MEETING OF STATES PARTIES (6–10 DECEMBER 2010)

Following the success of the Meeting of Experts in August, the Chairman wrote to the states parties on 15 October to encourage them to pursue an "action-oriented product" for 2010 that would be of practical assistance to all states parties and enable them to take effective action in building capacity for dealing with disease.

Participating at the December meeting were representatives from 92 states parties, four signatory states, one state not party, two branches of the United Nations,[10] five international organizations,[11] and twelve NGOs and research institutes. More than 450 participants took part in the discussions of the meeting.

The meeting began with a message from the Secretary-General, which was delivered by the Director-General of the United Nations Office at Geneva, Sergei Ordzhonikidze. This was followed by a general debate, during which 29 states, some on behalf of larger groups, made opening remarks. One observer organization, the OIE, also made a statement in the general debate. Following the general debate there was an informal session, during statements from 12 NGOs and research institutes were heard.

States parties began their working discussions with consideration of arrangements for the Seventh Review Conference and its Preparatory Committee, which will take place in 2011. The meeting approved the nomination of Ambassador Paul van den IJssel of the Netherlands as President of the Seventh Review Conference, and decided to hold the Preparatory Committee in Geneva 13–15 April 2011 and the Review Conference in Geneva from 5–22 December 2011. The rest of the discussion was devoted to the topic of the year, which was structured as follows:

- aims and challenges;
- building national capacity;
- preparing effective responses; and
- international partners and mechanisms.

The Meeting of States Parties also held a working session on the report of the Chairman on universalization activities[12] and the ISU report[13]. The entire Meeting of States Parties was conducted in public.

Following its adoption, the Chairman welcomed the report,[14] noting that the discussions held during the meeting constituted:

> "an important step in highlighting the challenges that the international community faces in responding effectively to the alleged use of biological weapons, and in finding ways to overcome these challenges. This document will act as a useful bridge to next year's Review Conference". The Chairman went on to say that the work of the Meeting illustrated that "States Parties are very well aware of the threats posed to international security by biological weapons, and realize that this meeting laid the foundations for future elaboration on this important issue".[15]

On the provision of assistance and coordination with relevant organizations in the case of alleged use of biological or toxin weapons, the states parties highlighted the importance of pursuing initiatives in the area through effective cooperation and sustainable partnerships. States parties underlined the importance of assistance being provided promptly, upon request, to any state party that had been exposed to a danger as a result of violation of the convention. As national preparedness contributes

to international capabilities, the Meeting of States Parties recognized the importance of states parties working together to build their national capacities, notably in the area of disease surveillance and detection, including through promoting and facilitating the generation, transfer, and acquisition upon agreed terms, of new knowledge and technologies, consistent with national law and international agreements, as well as of materials and equipment.

The Meeting of States Parties succeeded in agreeing a comprehensive range of common understandings (Annex). These understandings fall into two areas. Some are measures for responding to an alleged use of a biological weapon and include:

- eight security components;
- access to seven health components;
- six different approaches; and
- five areas in which states parties might work together.

Other understandings cover the roles of various actors when responding to an alleged use of a biological weapon and include:

- five elements of particular importance for the BWC;
- five distinct outstanding challenges;
- four areas where there are clear roles for states parties to play; and
- three ways in which international organizations are encouraged to focus.

CHAPTER 8

BUILDING A REGIME TO SECURE BIOLOGY IN THE TWENTY-FIRST CENTURY

Piers Millett[1]

BUILDING INTERNATIONAL REGIMES

It has been pointed out elsewhere that these annual meetings have not been business as usual for the Biological Weapons Convention (BWC).[2] There is, however, a traditional approach to developing regimes to address the threat posed by weapons of mass destruction. The model has been developed over the course of several decades and is the result of considerable multilateral negotiation. Many of its defining features are reflected in the regimes in place to deal with chemical and nuclear weapons. As Ambassador Masood Khan pointed out in Chapter 2, these are the very same elements missing from the BWC.

This chapter provides some broader perspectives to frame subsequent chapters on the work of the BWC during the 2007–2010 Intersessional Process. It attempts to place recent efforts in a broader international context, looking at how they are helping the regime develop a new approach—one based on a network rather than an institution and one that may be closer to the needs of the community it services. Discussions as to how well different approaches meet the needs of both biology and biologists are conducted with the understanding that no regime nor model we might develop will be perfect. It is clear that there is still a long way to go before the BWC provides a comprehensive answer to the threat posed by biological weapons. The arguments put forward here are intended to illustrate that the 2007–2010 Intersessional Process contributes to broader efforts to secure biology and that through them states parties gain "added value" in their efforts to strengthen the regime.

A TRADITIONAL ARMS CONTROL AND DISARMAMENT APPROACH

During the course of the second half of the twentieth century, efforts to address a series of threats posed by specific weapons led to the creation of a standardized approach to arms control and disarmament. Such a model, tailored to a weapon system, can be found in place to deal with nuclear weapons (under the Treaty on the Non-Proliferation of Nuclear Weapons and the Comprehensive Nuclear-Test-Ban Treaty, and with the International Atomic Energy Agency) and chemical weapons (under the Chemical Weapons Convention and with the Organization for the Prohibition of Chemical Weapons). It can be characterized as both hierarchical and linear in nature. In general, such regimes are created when a distinct weapons-related threat has been recognized. The threat prompts the international community to act, which it traditionally does by negotiating a treaty. In the case of unconventional weapons, these treaties commonly prohibit the acquisition, proliferation and use of the weapon. In order to realize the aims of the treaty and to consolidate its operational aspects, action is usually taken on two fronts. Firstly, the membership of the treaty creates and funds an international organization to do much of the day-to-day work (exchanges of information, inspections, verification, develop and issue technical guidance, among others). This organization supports the activities of member states and may have limited interaction with relevant stakeholder communities. Secondly, member states themselves undertake actions to implement the treaty, such as regulating the actions of national stakeholder communities through appropriate legal and regulatory frameworks. The activities of these stakeholder communities are therefore overseen both at national and international levels.

There are five definable facets to this approach. Firstly, it will not be perfect—no approach can be. Secondly, they are intrinsically hierarchical. Thirdly, as they are negotiated internationally and are binding in nature, they are ultimately standardized, fixed and resistant to change or evolution. Fourthly, they centralize resources. The attendant organizations are provided with the expertise, facilities and staffing member states think are needed to implement the treaty (although this differs from regime to regime depending upon how much emphasis is placed on the organization). Finally, they primarily use technological solutions (that is, compliance with the treaty is assessed by determining who has what technology, where and for what purpose it is being used). Certain technologies (associated solely

with prohibited activities) are banned and other resources (which can be used for both prohibited and permitted purposes) are regulated. The majority of technology (for example, chemicals in the case of chemical weapons) falls outside the regime and remains unregulated. It should also be noted that these regimes do engage in some degree of human-centric activities designed to develop ethical, moral and social aspects, but this is often seen as outside of the compliance framework and ancillary to realizing the aims of the treaty.

How does this traditional approach to arms control adapt to dealing with biology? In some areas it fares quite well. Given that we currently rely upon a negotiated response among states, a traditional arms control approach provides a dedicated, international mechanism which provides for global coverage (through the eventual universalization of the treaty) and certainly leverages the power of states. Given the nature of treaty regimes, they provide a way to engage the new states (although arms control and disarmament treaty regimes, and especially those dedicated to unconventional weapons, have traditionally had difficulties in attracting the interest of many developing countries). The ability of this model to tap global capacity is unclear—although in theory it should have sufficient resources housed within its organization to achieve the stated aims, in practice this might not always be the case. There have certainly been assertions that these organizations are under-resourced.[3] There are, however, some downsides to the state-driven, technologically-centric approach. As these models rely primarily on a technological solution, they tend to invest much less focus on human-centric tools, which are so important in the biological sphere. Equally, the primacy of states in these regimes has raised significant hurdles to genuine stakeholder engagement.[4] Arms control and disarmament has traditionally been the preserve of ministries of defence and foreign affairs. This in turn has complicated efforts for multi-sectoral engagement and interaction with other departments and ministries. Overall, it is possible to identify both strengths and weaknesses of a traditional approach and to map out a series of areas in which it might be improved. But could the model itself be revised?

AN EVOLVED NETWORKED APPROACH

Mainly out of necessity, the BWC has not had access to many of the elements that make the traditional arms control approach work. It has

had to find alternative mechanisms to strengthen international peace and security. These procedures and practices have been developed through the additional understandings reached by the Review Conferences. Although developed without a predetermined plan, they have evolved across all articles of the treaty to address specific issues as and when they arose. The decisions of Review Conferences, whilst not legally binding, see states parties commit themselves to take certain actions. More recently, the work of Intersessional Processes (firstly between the Fifth and Sixth Review Conferences and later between the Sixth and Seventh Review Conferences) have led to the development of common understandings amongst states and stakeholder communities as to the types of activities that are important to secure modern biology.[5] Whilst the approach developed by the BWC is not completely separate from the traditional model (and is clearly still not perfect) the framework does seem to be different enough to warrant being described in a separate model. This new model—an evolved network approach—is better suited, it is argued, to the specifics of dealing with biological weapons.

So how does this model differ? Similarly to the traditional approach, a threat was identified—in this case biology being used for hostile purposes. This threat prompted the negotiation of a treaty—but one that differs in length and content from other unconventional weapons regimes. It still addresses the acquisition, proliferation and use of a weapon but does not include verification procedures, a declaration regime or a mandate for an organization. In other words, it did not provide for the hierarchical structure so often seen in the traditional approach. Rather it has had to act as an umbrella, drawing together relevant actors from a variety of backgrounds, including: member states, United Nations organizations, specialist international organizations, the private sector, professional and scientific bodies, as well as other relevant non-governmental organizations. Many of these actors spend the majority of their time and resources dealing with other issues. The BWC provides a space for them to focus on those areas in which their interests overlap in addressing the potential for biology to be used for malign purposes. As a result, it has had to find new ways of working with others. The BWC cannot hope to solve the biological weapons threat by itself. It is clearly one tool among many—but given its international remit and status it remains the primary global forum for addressing these issues.

Given a stated wish to focus on "effective action" and the fact that many relevant stakeholders are not (and as they are not states, can never be) party to the treaty, comparatively little of the BWC regime has been standardized or fixed in place.[6] Rather, as described above, it has developed organically over time. For example, the Implementation Support Unit, the only institutional support for the BWC, will cease to exist in 2011, unless it is the will of states parties to do otherwise. By adopting such a flexible approach, the difficulties of evolving to consistently resemble the nature of the contemporary risks they address are less apparent than they can be in other models.

Although precedent continues to play an important role, so does innovation—as can be seen be recent efforts to make the fullest use of information technology (webcasting BWC meetings), efforts to improve interactivity (using discussion panels), the adoption of non-traditional tools (using poster sessions to focus on ancillary issues) and the creation of mechanisms to foster networking and community-building (speed-networking).

Given the lack of an organization, the BWC has not centralized its resources. They remain in the hands of the stakeholder communities and distributed across the full breadth of the network. For example, aspects related to health are in the hands of public, animal and plant health communities, thereby minimizing chances of duplication of mandate, resources or infrastructure. This creates a strong requirement for significant improvements in communication between these communities. Inherent in this model are certain properties common to networks, including robustness, resilience and flexibility. The lack of centralization also ensures that dealing with biological weapons cannot be shrugged off as "someone else's problem" as there is no international body to take responsibility. This has helped to engender a greater sense of ownership and buy-in.

Finally, there is still no international consensus that it is possible to develop a technological solution to biological weapons. It is certainly the opinion of some states parties that it is not possible at the moment. As a result, the BWC cannot currently rely on a technologically-based model and has invested considerable time and effort in developing a more human-centric approach. The BWC has focused on a broad array of tools and approaches to alter the behaviour of the users of biology. It has looked at how the treaty is implemented through legislative and regulatory frameworks to

interdict and punish those intent on using biology to cause harm. It has worked on awareness-raising through education and outreach and tried to bring this issue to the attention of practitioners of biology to minimize the risk that prohibited activities occur through ignorance. It has worked with stakeholder communities to develop best practices and oversight measures to ensure that biologists start to have access to tools to secure biology and that the necessary procedures are encoded in best practices and codes of conduct. It has fostered the debate as to how we can secure biology whilst facilitating its use for peaceful purposes. Such an approach also helps to future proof the regime. Should a technological solution be found in the future, it is easy to envisage any resulting mechanism becoming another facet of the broader regime.

CONCLUSION

The evolved networked model adopted by the BWC does seem to result in a regime tailored to the specifics of securing biology in the modern world. It is typified by its partnerships: among states, inside states, and between states and stakeholders. It also works internationally but acts through, and draws its legitimacy from, a community of concerned actors. It attempts to find ways to balance leveraging the power of states against collaboration with stakeholder communities to work together and draw upon relevant capacity irrespective of where or in whose hands it is found. The BWC community actively seeks global coverage, is increasingly open for all to contribute and engages with players in the field of biology, irrespective of whether they are developed states, new states, the private sector or individuals. This model does seem to offer additional benefits for securing biology and is embodied in the work of the 2007–2010 Intersessional Process.

SECTION B

BIOSAFETY AND BIOSECURITY

CHAPTER 9

INTRODUCING BIOSAFETY AND BIOSECURITY

Georgi Avramchev[1]

The issues addressed in this book are of growing importance to us all as members of societies that stand to benefit from the application of biology for economic development, the fight against hunger and dealing with disease. At the same time, we are also collectively threatened by biology being used for hostile purposes. We are in the process of strengthening ties between the scientific and policymaking communities and together we can shape an environment which ensures that advances in biology and biotechnology yield as many benefits as possible, while minimizing their potential for malign use.

Throughout the course of 2008 and at many locations around the world, I have attended, participated in and chaired meetings dedicated to exploring how we can create this environment. Time and time again, the importance of balancing the pursuit of science (to safeguard our futures) with security (to protect our present) has been raised. I am now convinced that to do this, we need to create a space in which we feel confident that biological resources are being used responsibly, while allowing scientists to retain the necessary freedoms to pursue cutting-edge research, develop commercial applications, and continue to drive progress. Developing robust but practical biosafety and biosecurity regimes will help us achieve this.

In the context of the Biological Weapons Convention (BWC), it has been agreed that biosafety refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins; and biosecurity refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.

Both biosafety and biosecurity are designed to contain certain agents and restrict them to certain locations and for given purposes. Collectively, they reduce the potential exposure of laboratory workers, the public outside of the laboratory and the environment to potentially pathogenic agents. Combinations of laboratory practices, containment equipment and special laboratory design can be made to achieve different levels of physical containment. Two core concepts for effective biosafety and biosecurity include: primary containment to protect personnel and the immediate laboratory environment through good microbiological technique, laboratory practice and the use of appropriate safety equipment, as well as secondary containment to protect people and the environment external to the facility through a combination of facility design and operational practices.

The BWC is the international convention that bans the use of biology for hostile purposes. Although considered to be one of the major pillars of the international community dealing with weapons of mass destruction, in practice the BWC addresses how science interacts with society. The convention was created to ensure that the life sciences are used only for the benefit of humanity. It matches prohibitions (ensuring that the life sciences are not used for malign purposes) against protections for scientific freedom (enshrining the right to conduct scientific activities for peaceful purposes).

Members of the BWC realized at the turn of the century that because of the pervasiveness of biotechnology and rapidity of change and development in the biosciences, governments alone could not confront the threat of biological weapons in the traditional arms control sense. No government or international organization can hope to monitor the tens of thousands of small biotechnology facilities spreading around the world. The number of facilities and the capability of the technology are ever increasing, while the cost and size of the equipment drops steadily. BWC states parties have developed a new approach, one that incorporates the efforts of a broader community and not only those of the defence and security sectors. The BWC now also actively pursues partnerships with the public health, agriculture, law enforcement and education sectors, as well as the international scientific community and commercial industry. If the potential problem lies in many hands, runs the logic, so must the solution.

CURRENT INITIATIVES

The BWC currently meets each year to consider ways to improve implementation. It hosts two meetings: one in the summer, at the "expert level", where world experts on technical aspects of the issues under consideration assemble; and the other at the end of the year, at the "diplomatic level", to consider how best to place the technical discussions of the Meeting of Experts into the political framework of the BWC. These meetings deal with issues agreed upon by all members in advance and are those thought to be particularly important in the global fight against the deliberate spread of disease. They help the convention's efforts to stay relevant in a rapidly evolving world. Part of our efforts during the 2007–2010 Intersessional Process focused on biosafety and biosecurity. In 2008 the BWC dealt with "national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins".[2] It also covered oversight, education, awareness-raising and adoption and development of codes of conduct which will be covered in the next section of this book.

The Meeting of Experts convened in Geneva from 18–22 August 2008 to begin work on these important topics, both of which go to the heart of improving effective national implementation of the convention. Participation in the meeting was impressively broad: 96 states parties were represented, and just under 500 delegates participated in the meeting. Of these around 180 were experts who had travelled from capitals. Importantly, there was strong participation from developing countries: 53% of the participating states were developing countries, up from 51% in 2007 and 48% in 2005. In the lead up to the Meeting of Experts, I asserted that this was an opportunity to "Bring Biologists on Board" and we certainly managed that. The meetings generated a great deal of relevant information, including background and working papers, statements and presentations, panel discussions as well as compendiums of national approaches. When the Implementation Support Unit (ISU) extracted the various substantive ideas and proposals, the list was 40 pages long.

The challenge was then to process this raw data to make it more manageable, accessible and useful. This was the job of the Meeting of States Parties. For this reason the tag-line of this meeting was "Refinement, Structure and Focus". As a first step in this process, I had the ISU process the raw data to remove duplicates, combine common points and structure

it in a more logical manner. This document was fed into the Meeting of States Parties as a tool to help states in their preparations. This synthesis, however, is more than a tool for diplomats. It has already been adopted by "in-the-field experts" and used as the basis of at least one assistance programme to strengthen a national biosafety and biosecurity framework.

During the course of the Meeting of States Parties, which was held in Geneva from 1–5 December, the content of the synthesis document was reviewed, debated and distilled to a series of common understandings. These understandings form the core of the output of this year's meetings and represent a shared vision amongst the members of the BWC, as to what they need to do at a national level, for example, to improve biosafety and biosecurity.

STRENGTHENING MEASURES TO MAKE BIOLOGY SAFE AND SECURE

Having chaired the convention's work on biosafety and biosecurity, several important lessons have stuck with me: balancing the pursuit of science against safety and security is critical; there is a real need for proportionality to ensure that our responses match the risks; we need ways and means to assess, manage and communicate those risks; and finally, there will be "no one size fits all" solution, as it is clear that individual and local circumstances must be taken into account when addressing these issues. I believe these are principles that should govern how we shape efforts to strengthen biosafety and biosecurity provisions. They certainly run through the various outputs of our work in 2008.

During the course of the year the BWC meetings have produced a range of tangible outputs: background documentation acts as an important summary of thinking on these issues; reports of the meetings provide distilled versions of expert input; original inputs from experts from around the world, when combined, also form an important resource—one which is unique in both its size and its variety; the working documents, which retain enough details to be useful whilst being sufficiently refined to be practical, have become important tools in their own right; and equally, some tools, such as the compendiums of national approaches, will continue to be updated and evolve as additional information become available—hopefully proving useful input for future efforts.

But not all of the outputs are so easily quantifiable. BWC meetings have also provided important opportunities for networking, collaboration and community building. If the rhetoric of creating a shared solution to a common problem is to have meaning, we must have a sense of community amongst those of us working on these issues. Perhaps the most important intangible contributions made by the BWC this year are towards this sense of community. Participating in meetings like those that make up this Intersessional Process, seeing old and new friends in different locations, at different times and playing host to such activities in Geneva, have convinced me that a real community does exist and that it is vibrant, enthusiastic and an integral part of any solution.

Both the tangible and intangible outputs have enabled the BWC to make some concrete contributions to improving the way the BWC works as well as to efforts to strengthen biosafety and biosecurity, including:

- Reaching a common understanding on what is meant in this context by the terms: both biosafety and biosecurity have different meanings in different contexts. To ensure that we are all working on shared objectives, it was important that our work in 2008 reached a shared view on the scope of these terms.
- Forging new relationships between the BWC and the scientific community: 2008 saw a distinct change in the way we work in Geneva, increasing access for scientists and as a result we drew record numbers of expertise to our meetings.
- Improving engagement with industry and the private sector to make discussions more representative of the status of global biotechnology: dedicated events were held to illicit the views of members of the private sector and this provided new insights. The year 2008 also saw higher levels of participation from developing countries making our discussions more geographically representative.
- Making space for contributions from international and regional organizations, as well as professional and scientific societies and academia: the BWC meetings in 2008 had dedicated working sessions, side events, panel discussions and poster sessions, all to provide opportunities for input from stakeholder communities.
- Exploring the value of risk management: the Meeting of Experts included a panel discussion dedicated to risk management, and their

discussions directly influenced the output of the meeting and our work later in the year to develop common understandings.

- Producing authoritative sets of information: the background papers provide a comprehensive snapshot of the state of affairs. The papers and presentations made during the meetings are an unparalleled dataset and the compendiums provide easy access to details of relevant activities being undertaken in different countries.
- Developing new tools to improve the way we work and share information: the inclusion of poster sessions in our timetable was universally appreciated. Efforts to create new online tools, such as the compendiums, have added depth to our meetings. Interactive elements, such as the panel discussion, help us to make the most use of the expertise present at BWC meetings.
- Identifying useful components for developing or revising national regimes: the breadth and depth of the common understandings found in the report of the Meeting of States Parties more than met expectations as to what we could achieve and is testimony to the dedicated and constructive efforts of the states parties.

CONCLUSION

Biology is booming. Biotechnology is advancing at an unprecedented rate and beginning to find applications that have a direct impact on the way we all live our lives. Biology offers us benefits for health, agriculture, industry, manufacturing and the environment. We cannot afford to see progress in these fields impeded. Biotechnology capacity must continue to spread around the globe, and its benefits must be widely shared. The challenge that confronts us now is how best to ensure that these powerful new capabilities yield as many benefits as possible, while minimizing their potential for malign use. We must find new and improved ways of working together and develop understandings and approached shared across geographic, cultural and sectoral boundaries. I believe that the BWC meetings in 2008 made a giant leap forwards towards achieving this goal. I hope that we are able to build upon this progress over coming years and that all relevant stakeholder communities will be active partners in these collective efforts.

CHAPTER 10

A SUMMARY OF THE PANEL DISCUSSION ON RISK GOVERNANCE

Piers Millett

The risk governance panel at the 2008 Meeting of Experts took place on 20 August 2008.[1] On the panel were:

- May Chu, a microbiologist and specialist in laboratory systems with the World Health Organization (WHO);
- Iain Gillespie, Head of the Biotechnology Division of the Organisation for Economic Co-operation and Development (OECD);
- Keith Hamilton, laboratory expert of the Scientific and Technical Department of the World Organisation for Animal Health (OIE);
- Paul Huntley, a principal consultant for biological risk assessment at Det Norske Veritas;
- Brook Rogers, an expert on risk communication at the King's Centre for Risk Management, King's College London; and
- Cathy Roth, Coordinator of the Biorisk Reduction for Dangerous Pathogens Team of the WHO.

OPENING REMARKS

Following introductory remarks by the Chairman, each of the panel members was given an opportunity to make a short statement.

Dr. Gillespie focused his remarks on the risk governance framework under development by the OECD. He pointed out that although there is "no one recipe" for governing risk that it was possible to put together a framework of elements that could then be tailored to specific uses. He

discussed each of the key elements that such a framework should have and stressed the dynamic and non-linear nature of governing risk. He concluded by describing a series of important practical considerations for risk management.

Dr. Hamilton expanded upon relevant activities pursued by the OIE, including their links with organizations dealing with different types of biological risks; their role in standard setting; relevant publications and manuals (such as the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, *Terrestrial Animal Health Code*, *Aquatic Animal Health Code*, among others); the risk groups currently used by the OIE and the associated containment principles; and OIE publications on carrying out quantitative and qualitative risk assessments for the animal trade.

Dr. Huntley focused his remarks on practical insights gained from his experience in doing risk assessments and planning risk management. His insights covered both risk assessment, from "what is risk assessment" to "developing a risk determination matrix" as well as risk management. He looked at both standard methodologies and common problems in implementation. He concluded with thoughts on what is needed to improve the utility of governing risk.

Dr. Rogers introduced the activities of her project and organization. She reviewed some of the academic work taking place in risk communication, especially as they relate to psychology and risk perception. She talked about national and regional projects (with both international organizations and first responders) to identify what messages are effective and how information can be communicated more effectively. Dr. Rogers also identified a series of important lessons for communicating risk to various different audiences.

Dr. Roth and Dr. Chu looked at practical examples of risk governance in the day to day work of the WHO. They focused heavily on the way the WHO gathers, assesses and responds to reports of relevant disease outbreaks, as well as the implementation of the revised International Health Regulations. They extrapolated a series of concepts that related to each aspect of the governance framework and applied them directly to biosafety and biosecurity.

BIOLOGICAL RISKS AND THREATS

The use of biological weapons (deliberately causing disease outbreaks or incidents of poisoning) is not the only type of risk to involve biological agents. There are also accidental and natural causes for disease. Given that the meetings in 2008 were tasked with looking at both biosafety (to prevent accidental releases) and biosecurity (to prevent deliberate diversion), it was clear that discussions over biological risks could not be confined solely to weapons issues. On a practical level it is difficult, if not impossible, to differentiate between various risks. If an incident involving a biological agent were to occur, it is unlikely that it would be possible to immediately identify what type of biological risk had caused it. One cause tends to be closely connected to other. In fact, the various possible causes of disease events were characterized as being part of a spectrum ranging from natural causes, through unintended consequence, accidents, negligence and sabotage all the way to deliberate use.

As biological risks can have a set of interconnected causes, it was suggested that efforts to manage them should also be interconnected. As a result, efforts to deal with any issue on this spectrum should provide benefit for as much of it as possible. Improved coordination could lead to efforts under the BWC providing spin off benefits for dealing with natural and accidental disease. Equally, parallel initiatives undertaken in other setting could be of use in addressing biological weapons. Dealing with interconnected risks in a more holistic manner minimizes the risk of "wheels being reinvented" and ensures that limited resources are used in an optimal manner. Such a broad-spectrum approach to dealing with biological risks is already a reality in certain circles. The WHO, for example, works to reduce biological risk irrespective of whether it has a natural, accidental or deliberate origin.[2] Conceptual development under the convention is not so well developed. The challenge for the BWC is to identify toolsets, common in other settings, which might be adapted to deal with deliberate acts. Risk governance was suggested to be one such tool.

THE RISK GOVERNANCE FRAMEWORK

The panel arrived at a common understanding that a framework for governing risk would need to retain the sufficient flexibility to allow details to be adapted to precise regional, national and local circumstances, whilst

being concrete enough to be of practical assistance. Panellists shared a common view that a framework should encompass risk assessment, risk management and risk communication. It was also pointed out that risk governance is not necessarily a linear process. Risk management does not have to follow risk assessment (in fact the two were described as being in a feedback loop where the results of one step automatically influence the other) and risk communication does not have to wait until both assessment and management steps have been completed (several panellists argued that risk communication must be incorporated into every step of assessing and managing biological risks).

RISK ASSESSMENT

Risk assessment allows the practitioner to examine the nature of the danger that is of interest—in this case biological agents and toxins accidentally or deliberately causing disease or poisoning. It looks at the likelihood and consequences of a given hazard-event happening. Risk assessment encompasses a number of discrete activities, including *risk identification* (what should we be examining in more depth) and *risk determination* (to characterize the likelihood of the hazard being manifested and the likely consequences of such an event). When developing and carrying out risk assessment procedures, it is important to remember the contexts in which they will be used (available resources, methods of communications, among others).

Risk identification

Risk identification is based upon the nature of the hazards involved—in this case the characteristics of the biological agents and toxins. If an agent is highly infectious, it can spread more easily—the more pathogenic, the more likely an infection will occur, and so on. Such characteristics affect risk but are fixed and quantifiable in advance. It possible to classify this facet of risk based upon infectivity, pathogenicity, environmental resistance and the existence of prophylaxis or treatment, among others. For example, the OIE has developed four risk groups (where group one poses the lowest risk and four the highest) to which individual animal and zoonotic pathogens are allotted. Human intervention, procedures and external factors all also play an important role in identifying risk.

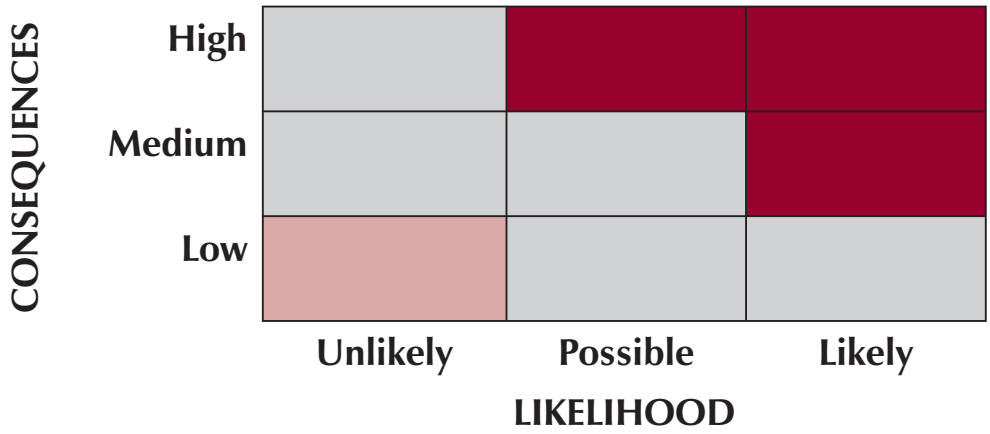
A second theme picked up by the panel was that of information asymmetry. Practitioners skilled in carrying out day-to-day assessments often lack a fully developed understanding of broader issues (such as diversion for weapons purposes), and those familiar with unusual aspects of risks and threats are often less familiar with the more day-to-day activities of the practitioners. There is often a disparity of information and effective risk identification can be dependent upon how relevant information is exchanged. Ultimately a risk assessment will only be as good as the information that was fed into it. For example, one use of risk identification is to establish whether a disease event is actually taking place (which would dramatically alter the assessment of the risk posed by that disease in a given time and place). Information can include expert opinion and unconfirmed data and come from both official sources (health professionals, reporting systems, reference laboratories, among others) and from informal sources (such as through the media, on the internet, from non-governmental organizations and the general public). Different sources of information must be dealt with in different ways. It is important to find ways to "boost the strength of the signal", reduce the background noise and extrapolate out the relevance of the information in hand. Whatever system is developed for identifying risk in a given context, it is important that it takes place in a transparent manner so that it is always possible to understand how the result of an assessment was derived.

Risk determination

Risk determination can be approached quantitatively (using mathematical probabilities), qualitatively (through subjective assessment) or through a combination of the two. In practice, it is often difficult to obtain sufficient data to be able to fully characterize either likelihood or potential consequences of an event that has yet to happen.

A qualitative assessment can often be made more rapidly and with less information. It can be useful to group together assessments, making an event "unlikely" or "rare", rather than trying to be too specific (like saying there is a 27.4% chance of it happening). Consequences can also be grouped in multiple categories, allowing for easy comparison. This enables a simple matrix to be developed, where the level of risk can be determined to be red (unacceptable), grey (needs to be managed) or light red (acceptable risks) (see Figure 10.1).

Figure 10.1 A risk determination matrix



Notes: Allotment of each cell as red, grey or light red in this example is arbitrary. Thresholds for acceptable or unacceptable risks are usually set by the affected communities.

If more data are available and the resources required to process it, a quantitative analysis might be more useful. By expressing risk mathematically, it is often easier to compare relative risks—there is a 27% chance of risk A happening, compared to a 68% chance of risk B. This can also be used in determining how useful a particular strategy is in managing risk—doing X will reduce the risk by 14%, whilst Y will only reduce it by 2%. Such modelling can be complicated, requiring both highly trained individuals and access to computer hardware and software.

Advice on risk determination included:

- Avoid complicated methods when simple ones will do.
- Determining risk levels related to biological weapons issues is particularly difficult given the small existing data set, the lack of recent data and the impact of human interaction and intent.
- Competing understandings of terminology impede effective assessment (such as what is actually meant by “likelihood” and “consequence”).
- Consequences are almost always interconnected—it is unlikely that an event would only have one type of consequence (for example, purely security implications). There would normally be multiple consequences, some of which might not be of direct interest but

nevertheless should be included in the assessment as they will influence the ultimate level of risk.

- Given the number of parameters involved in effective risk determination, common standards, reference points and language are critical.

RISK MANAGEMENT

Risk management is the process by which preparedness and response efforts are tailored to reduce a perceived or actual risk (as described through risk assessment). It is based upon a belief that whilst risks cannot be completely removed, they can be reduced to such an extent as to make them an acceptable cost of doing business. Core risk management concepts include:

1. It is never possible to remove risk completely—there will always be some residual risk if an activity is undertaken. The aim of risk management is to reduce it to an acceptable level. This necessitates an active decision of what level of risk is acceptable.
2. There is a need for proportionality—to ensure that preparations and responses are proportionate to the consequences and likelihoods. Over-engineering for the sake of it should be avoided.
3. Make sure human factors are addressed in assessment and management strategies—although as humans we are bound to make errors that would influence the levels of risk and our ability to manage them, we also innovate and evolve, so human factors can also be an asset.
4. Standards and best practices work better than legislation and regulation—there is no "one size fits all" approach to risk management. It is possible to harmonize the different approaches and techniques. This requires flexibility, which can be best achieved through standards that can be applied and best practices that can be used, rather than rules that must be enforced.
5. The differences between licensing, certification and accreditation—a state-based licensing system generally allows you to enter a field, whilst certification (having certain procedures in place) and accreditation

(demonstrated competence in applying those procedures) prove that you have an ability to work in the field.

A basic risk assessment of a biological agent allows precautionary measures to be implemented according to the hazard it poses. For example, the risk posed by a given agent is assessed and allotted to one of the four OIE risk groups. Precautionary measures, designed specifically to counter the characteristics of the risk groups can then be developed and employed. In the case of OIE this would mean utilizing containment measures comparable to the risk (once again where containment level one is the least stringent and is used for the lowest risk agents and where level four is the most demanding and is reserved for agents that pose the greatest risk).

When considering what sorts of questions might need to be asked when establishing measures to manage biosafety and biosecurity risks, the panel included:

- Is the risk a result of a random or systematic error?
- What kind of remedial actions will reduce the risk immediately?
- What kind of remedial actions will reduce the risk in the longer term?
- How can we minimize the chance of this risk happening again?
- Are the resources on hand to respond to this risk?
- Will assistance be required to respond to this risk?
- Do others (including other states) need to know what has happened?
- Should an event resulting from this risk be reported (if so to whom)?

RISK COMMUNICATION

Risk communication is the process through which the details of risk assessment and risk management approaches and practices are shared with various audiences, from policymakers, those on the front line and the general public. Discussions on risk communication highlighted the importance between actual risk and perceived risk. Just because the analysis of a potential risk suggests it is unlikely or would have a minimal consequence does not mean that a community will see it that way. Other social factors come into play, and to be able to address perceptions of risk

it is often necessary to combat fear, "group think" and Zeitgeist. This can be best combated through familiarity with the topic. This means that the messages being broadcast have to be efficient and effective.
It was also noted that often experts and the general public think about risk in very different ways and might have distinct differences on what is acceptable and unacceptable. They also respond to risk differently. A well-informed expert might take the time to weigh up alternatives and come up with a course of action in a logical manner. A member of the general public, who is less likely to have a familiarity with the subject matter or have been exposed to all the facts, figures and options (as well as the reasoning behind them) might act in a unpredictable or even counterproductive manner. This requires that messages have their intended impact, which often means explaining why people should follow recommended protocols.

How people actually respond to an event can also influence the effectiveness of the response and, therefore, morbidity and mortality rates. For example, if fear-motivated flight overcomes advice to stay isolated in an area with an outbreak of an infectious disease, additional people might be exposed to the agent. Therefore, effective risk communication is not only a public-relations exercise, it is a critical part of health preparedness, mitigation and response. As such, it was recommended that risk communication is not left until an event has occurred. Familiarity with terminology, response measures and why such measures are necessary can all help to address fear-induced responses. The value of pre-event communication was noted.

It was also suggested that more needs to be done on an ongoing process. Whilst progress is being made in getting the message out that biological risks and threats (including biological weapons) are an issue, much less is done to inform others about what they should do. It is also important to communicate that effects can be treated and managed, that chances of survival can be improved if certain steps are taken (as well as saying what those steps are), and stressing the importance of timeliness in dealing with biological risks. It is important to keep communicating as situations change—why has some advice been changed, how is safety and security improved by the changes, how policymakers are continuing to work to minimize risks and threats and what this means to people in their daily lives.

CHAPTER 11

BIOSAFETY AND BIOSECURITY CONCEPTS AND APPROACHES

Isabelle Daoust-Maleval

In the long term public-health concerns are the main objectives of states implementing biosafety and biosecurity concepts on a global scale. Thus, biosafety and biosecurity respond deeply to the need to ensure global public health. For the population, the workers and the environment, the goal is to prevent their exposure to harmful biological agents and toxins. This exposure could be unintentional—originating from accidental release—or could also be caused by loss, theft, misuse, diversion of, unauthorized access or intentional release of biological pathogens.

For this reason the Fifty-Eighth World Health Assembly considered that the release of microbiological agents and toxins may have global ramifications. It acknowledged that the containment of microbiological agents and toxins in laboratories is critical to preventing outbreaks of emerging and re-emerging diseases such as severe acute respiratory syndrome (SARS), and it noted that an integrated approach to laboratory biosafety, including containment of microbiological agents and toxins, promotes global public health.[1]

In October 2001 several letters containing highly infectious anthrax spores were mailed in the United States to news media offices and two US senators. The letters killed five people and infected 22 others, rapidly spreading panic among the population. As a consequence, extensive public-health measures were implemented for the treatment and care of thousands who were potentially exposed to anthrax. The decontamination of the government buildings and postal offices took years. The overall damage cost more than one billion dollars.

There is increasing awareness of the importance of both biosafety and biosecurity. Many states have begun to engage in these issues, and action

has been taken at international, regional and national levels. This chapter introduces concepts of biosafety and biosecurity. It looks at them as a continuum that forms the basis for biological risk (biorisk) and examines how we deal with it. Without a proper assessment of what the risk is, it is not possible to know from what we need to protect ourselves or to identify gaps in the system to put in place biosafety and biosecurity measures to manage the risk. A proper assessment of the risk will allow for a proper management strategy to be developed. Such a management strategy will likely make use of existing standards, require a national legislative and regulatory framework as well as take advantage of quality management systems—especially those that lead to accreditation, that is to say those that take into account a sound management, an overall traceability and an assurance of staff competence.

CORE CONCEPTS

This section introduces core concepts used in the remainder of this chapter, as well as throughout the rest of this book. Wherever possible, definitions have been taken from relevant authoritative international texts.

Biosafety and biosecurity

Perhaps the most widely known uses of the terms biosafety and biosecurity[2] (and the one most relevant to the Biological Weapons Convention) are derived from publications of the World Health Organization (WHO). In the WHO *Laboratory Biosafety Manual* laboratory biosafety is described as "the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release".[3] In *Biorisk Management: Laboratory Biosecurity Guidance* the WHO describes laboratory biosecurity as "the protection, control and accountability for valuable biological materials [...] within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release".[4]

Biorisk

A useful definition for this term can be found in the specifications for an international occupational health and safety management system from the Occupation Health and Safety Assessment Series (OHSAS 18001).[5] Biorisk

is described as the combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence of such an exposure.[6] As a result, biorisk can result from both accidental and deliberate release of such agents and toxins (as well as events with a natural origin).

Measures to address biorisk encompasses both biosafety and biosecurity provisions. The term came about as a result of the different uses and schemes that have been established for laboratory biosafety and biosecurity.

Distinctions between the two terms are quite academic—in practice, when one is actually working hands-on in a laboratory it is more difficult to draw such distinctions. At the operational level there are many similarities between the two.

Biorisk assessment and biorisk management systems

Biorisk analysis is the process of evaluating the biorisk arising from hazard or VBMs,[7] taking into account the adequacy of any existing controls, and deciding whether or not the biorisk is acceptable. Assessing biorisk in this manner allows measures to be put in place to reduce this risk. Collectively, these measures can form a biorisk management system.[8]

DEALING WITH BIORISK

There is thus a continuum between biosafety and biosecurity, with two driving forces: biorisk assessment and biorisk management. For an overall review of biological risks, and from a technical and pragmatically point of view, the following step by step approach has to be considered.

Step 1: assessing biological risks within and outside laboratories

This approach allows gaps to be identified and failings to be understood. Without a proper assessment of what the risk is—closely linked to the types of conducted activities—it is not possible to identify against what to protect ourselves or to identify gaps in the system. Thus, it is not possible to implement suitable biosafety and biosecurity measures. A proper

assessment of the risk will allow the development of a proper management strategy.

If a release from a laboratory were to occur, the significance of the leak and its consequences would depend upon the type of environment outside the laboratory and the national preparedness and response measures. It is necessary to take into account the health situation of the country, which can also impact upon the significance and consequences of a release, including: whether a population has been vaccinated against a specific type of risk; whether capacity exists for an effective government response; and the local population density, which will determine person to person transmissibility ratios.

Step 2: implementing an effective biorisk management system

Such a management strategy will likely make use of existing standards, require a national legislative and regulatory framework as well as a proper quality management system. Hence, there is no "one size fits all" comprehensive response to biorisk.

Biorisk management systems—understood as a global approach—are often dealt with through a number of interconnected and complementary responses, taking advantage of different types of measures and requirements coming from international standards, international best practices and recommendations (such as WHO manuals), as well as laws and regulations (European or national), which deal with specific aspects of the risk both within and outwith laboratories (such as during the exchanges of pathogens between laboratories). For this reason it is mandatory to adopt a global approach—such as an integrated management system (IMS). This takes into account the different types of measures and requirements that have to be applied at the laboratory scale—considering not only the types of activities but also the strategic policy defined by the directorate—as well as for the activities that occur between laboratories.

Some measures deal with the prevention of the biorisk within laboratories, others deal with those derived from exchanges of biological agents and toxins between laboratories. Each state needs to develop its own laws and regulations for dealing with biosafety and biosecurity. Both biorisk assessment and management strategies will depend on the national situation, and should take advantage of existing standards and guidance,

and provide practical tools at the operational level. The requirements are legally binding when they come from legislations and regulations; others are applied on a voluntary basis by the laboratories, when they come from standards, or international recommendations.

In France the legislative and regulatory framework takes into account the idea of biosafety and biosecurity forming a continuum.[9] This translates into a requirement to carry out biorisk assessments in the laboratory taking into account types of strains, quantities used, infectious doses, types of experiment, biosafety level and other such criteria.

These assessments allow management strategies to be tailored to the circumstances of specific facilities through the development of recommended operating procedures for effective and reliable biorisk management. Such procedures should serve a specific purpose which fills an existing gap or overcomes a current shortcoming. We have found that quality management systems can often achieve this. Although not related explicitly to biosafety and biosecurity, a number of relevant standards for setting up quality management systems do exist: standards to coordinate activities to direct and control an organization with regards to quality (IS0 9001:2008),[10] standards for environmental management systems (ISO 14001:2004),[11] and standards for health and safety management systems (OHSAS 18001). These standards are the basis of the quality, security, environment (QSE) approach.

INSTITUTIONAL MANAGEMENT OF BIORISK

International, regional and national initiatives should provide tools to assist in the implementation of biorisk assessment and management strategies at the institutional level. Quality management systems provide a useful model. They are used to demonstrate an ability to meet consistently the requirements of both customers and regulatory systems and provide mechanisms to improve systematically a systems ability to do so. The first requirement of these quality management systems is to have exhaustive traceability—quite useful in sourcing accidental mistakes. Nevertheless, they also could be a powerful tool to identify as soon as possible a "deliberate" mistake—that is to say a malevolent act.

Others standards—such as ISO/IEC 17025:2005,[12] with general requirements and ISO 15189:2007,[13] dedicated to medical laboratories—take into account the traceability but also the competency of the staff, which is a real key point regarding biosafety and biosecurity. An effective laboratory biorisk management system is based on a quality management system with two main driving forces enforced by an international standard such as ISO/IEC 17025:2005—traceability and staff competency.

Traceability

Traceability is important because it enables an effective biorisk assessment to be carried out. It is not possible to identify risks if you do not know what is being used, when and where and for what. This is why we need an exhaustive traceability of the "resources" (that is to say personnel, premises, operations—which have to be conducted in compliance with validated methods—equipment and biological materials) used by laboratory to conduct its activities.

Staff competency

The second driving force is the requirement for staff competency. Since ISO/IEC 17025:2005 is an accreditation international standard, the competency of the staff constitutes the main requirement of the standard. The staff must be competent, knowledgeable and aware of what they are doing—qualities which are crucial both for biosafety and biosecurity. Competence is essential for evaluating risk, which is also true of managing risk. Regarding biosecurity, the requirement of staff traceability is important for security clearance.

Principles of good laboratory practices

Good laboratory practices (GLP) outline the best practice for carrying out scientific studies.[14] It describes how such studies should be organized and managed, taking into account test facilities, the study director and personnel aspects. They also deal with how studies are planned, controlled and recorded as well as how their results are diffused and archived. There are two key themes in GLP: the importance of the reproducibility and reliability of scientific studies; and their traceability.

The reproducibility and reliability of studies is very important in the commercial application of science, especially for the pharmaceutical sector. Agencies that license these products need to be sure that the studies that demonstrate their safety and effectiveness are reliable and that the results reported can be reproduced by a third party. In order to acquire a licence to produce a biological product, it will be necessary to demonstrate what is introduced into the process, where and when. In addition, it will be necessary to be able to track what happens to all the material used in the production process, as well as any waste or by-products to ensure that the process is safe. This requires effective traceability throughout the process life cycle. As a result, all facilities involved in the discovery and development process will need to have employed GLP.

Requirements for testing and calibration laboratories

Laboratories involved in the testing of products and samples, or which are used for calibration purposes, have to be reliable. Shortcomings in scientific practice in such institutions could have a significant impact on the validity of third-party science, the safety of products, as well as having health, environmental and economic implications. In an attempt to ensure the competency of such facilities, a series of international standards were developed—ISO/IEC 17025:2005. Accreditation under this standard allows a laboratory to demonstrate that they have an effective quality management system, are technically qualified and competent and are able to generate technically valid results. Compliance with this standard also necessitates meeting relevant requirements of general quality management standards under ISO 9001:2008 and ISO 9002:1994.[15]

Compliance with this standard also opens doors towards international cooperation and economic development. By being certified under this standard, results produced by a laboratory are more likely to be accepted elsewhere in the world. There are mutual recognition agreements and bodies built upon them that use this standard to facilitate cooperation between laboratories. This standard assists in the exchange of scientific information and experience as well as in the harmonization of scientific practices and procedures.

Nevertheless, ISO/IEC 17025:2005 comprises only general requirements but which can be the basis for an approach such as an IMS. Thus, we have to take into consideration not only the requirements of the standards for

environmental management systems (ISO 14001:2004) and the standards for health and safety management systems (OHSAS 18001) but above all the specific requirements—for the biological sphere—of the reference document dedicated to the biorisk assessment in the laboratories (CWA 15793).[16] Thus, it is not possible practically at the laboratory scale of taking into consideration only a part of the problem (for example, only the biological sphere). An IMS realizes the merging of all internal management practices into one single and unique system.

Standards for biological resource centres

Biological resource centres (BRCs) are:

> 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. micro-organisms, 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 data bases containing molecular, physiological and structural information relevant to these collections and related bioinformatics.[17]

In short, they are centres that hold and provide authenticated biological material in a sustainable and long-term manner. In order to accomplish this safely and securely, certain accreditation and control processes are needed. According to the model developed under the *OECD Best Practice Guidelines for Biological Resource Centres*, BRCs should be accredited nationally to certify their competency. This also means that their activities are the responsibility of governments and those transfers of relevant biological materials are ultimately under government control. In order to ensure that basic safety and security provisions are met, this requires a high degree of traceability. Through the development of international quality control standards there is also mutual traceability and the de facto creation of a global BRC network.

At a practical level the quality management system chosen by the OECD is ISO/IEC 17025:2005, which could be usefully complemented by the Common Access to Biological Resources and Information (CABRI) guidelines.[18]

The complementarities of responses facing biorisks which are different in nature could be measures within laboratories (for example, through the compliance to standards such as ISO/IEC 17025:2005 taken as a general framework that needs to be supplemented by specific measures to the biological applicability) regarding the five interconnected aspects of the operation of a BRC: personnel, premises, operations, equipment used and biological materials.

- Personnel—when managing biorisk, the aim is to know who is doing which activities and to define specific and relevant responsibilities. This allows regulators to ensure staff are operating within their competencies and training programmes are conducted, ensure the availability of protective equipment, and allow for staff traceability.
- Premises—ensuring that there are appropriate levels of containment, and appropriate hygiene and cleaning procedures are implemented. Traceability measures, such as controlling access and ensuring the presence of appropriate arrangements for site security can improve biosecurity.
- Operations—designed to ensure that regulators know what is happening where. Optimizing operational aspects of a BRC to take into account biorisk will require a range of different competencies, including animal experimentation if needed. Ensuring safe transportation of the strains and samples, effective decontamination, cleaning and processing of waste at a BRC will enhance biosafety. Operational steps that might need reviewing in light of biosecurity considerations include: checking biological materials against a dangerous materials list prior to accepting them; receipt and storage of the initial sample; transportation of the strains and samples, preparation generation, handling and processing of samples; preparation, and sterilization of culture media and equipment; biological material storage; and the supply, delivery and sale of samples.
- Equipment—it is important to ensure full traceability of each and every operation to enhance biosecurity. Ensuring competent maintenance, such as effective cleaning and decontamination, can improve biosafety. This can be reinforced by implementing a contamination monitoring programme and putting in place measures to investigate the source of any contamination that might occur.

- Biological material—it is important for both biosafety and biosecurity to have full life cycle traceability. This should include: acquisition criteria[19]; registration of each operation involving the material; quality controls (competence) based upon the CABRI guidelines, such as preserving samples, distribution, stock control, storage and recording of data; packaging requirements that comply with current transport of dangerous goods, postal, quarantine and International Air Transport Association regulations; as well as records of all requests for biological materials (even those refused), detailing materials requested, method and date of shipment, and name and address of the recipient.
- Biosafety and biosecurity go hand in hand, and a global approach regarding biorisk management systems is thus mandatory and must take into account of any kind of activities (within the laboratory but also outside the lab during the exchange of biological materials) and requirements coming from any state legislation and international standards.

CONCLUSION

General quality management systems, complemented by specific reference documents devoted to the biological sphere, have to be understood as a basis for encompassing biorisk assessment and biomanagement systems. Such an IMS enables a global approach to ensure safety and security in the biological sphere. An IMS is relevant to integrate several standards into one cohesive system with a holistic set of documentation, policies, procedures and processes.

Thus, ISO/IEC 17025:2005 has to be taken as a general framework that needs to be supplemented by specific measures linked to biological applicability. This is the core approach to addressing biorisk. A number of tools have been developed to help conduct risk assessments and implement management systems. These tools need to be shared more widely to develop a common culture of addressing biorisk and to improve biosafety and biosecurity provisions around the world.

CHAPTER 12

CASE STUDY I: BIOSAFETY AND BIOSECURITY IN PAKISTAN

Aamer Ikram

> I am not sure what weapons will be used in World War III, but World War IV will be fought with sticks and stones.
>
> Albert Einstein

BACKGROUND

We are sitting near the tip of an iceberg, where we are surrounded by millions and billions of micro-organisms. Any unnecessary manipulation with these tiny creatures can instigate havoc and disaster with life in any form. There is diverse array of aetiologies, such as bacteria, viruses, fungi and toxins, but the spectrum has grown much broader with the evolution and advancement in genetically modified organisms (GMOs). The foremost concern is to beware of the associated biohazards when dealing with such biological materials and even more so during manipulation. These organisms observe no boundaries and as such enforcement of rules and laws becomes mandatory for us to be cautious with them.

World Health Organization (WHO) guidelines are very precise and elaborate in this regard.[1] These clearly highlight the concepts regarding the codes of practices to be followed at the laboratory level. Biosafety and biosecurity are very much interrelated, based upon the three indispensable components: prevention, control and surveillance. Any intentional or unintentional neglect of these basic constituents can trigger colossal damage not only to mankind but to all other forms of life as well.

The Cartagena Protocol is a substantial achievement for delineating the role of biosafety in the modern scientific research.[2] Modern biotechnology

remains dual edge with advantages to human life and environments on one spectrum to gauging the adversaries on the other. The protocol encompasses the transboundary movements of living modified organisms and GMOs. As far as developing countries are concerned, the aspect that has to be underscored is that they are particularly confronted with certain challenges with this protocol. The evident reason is that their ability to develop, impose and monitor biosafety laws is in the nascent phase. Furthermore, certain issues in the protocol have been left to the national discretion. These issues are to be addressed while balancing their rights and obligations under the protocol vis-à-vis their commitments under the present international scenario.[3] The diversity of opinion may arise due to certain factors such as appropriate degrees of protection of human health or environment, types of risk with acceptable levels, interpretation of risk constitutes and the availability of scientific evidence, the expediency and efficiency of risk management measures and the magnitude of socio-economic factors.

As far as the select agents and infectious agents are concerned, it is mandatory that the possession, use and transfer of specific biological agents should be guarded under high security and containment must be maintained under all circumstances. The list of select agents has to be clearly classified. The perspective of biosecurity has widened with the present day scenario. Proper monitoring and oversight at research institutes has to be maintained with greater vigilance.

The Biological Weapons Convention (BWC) has played a pivotal role and provided an excellent platform so that most of the issues are continually being resolved through deliberations. The strategy to be adopted for enforcing biosafety and biosecurity is multifaceted. The process starts with formulation of prudent guidelines, followed by information dissemination, accomplishment through intensive training, upholding strict implementation of rules and regulations and pursued through regular reviewing of the situation. The standard can only be set forth with exquisite efforts at national and local levels.

NATIONAL BIOSAFETY COMMITTEE

Pakistan has demonstrated the utmost commitment to these international obligations. To that effect, the biosafety rules were launched in 2005, and

the same year the biosafety guidelines were introduced.[4] The rules are applicable to micro-organisms and GMOs with regards to the manufacture, storage and transfer at research and diagnostic institutes or laboratories at any level. Presently, there is fully functional National Biosafety Committee (NBC) headed by the Secretary of the Ministry of Environment. It has representation from four ministerial departments: health, food and agriculture, science and technology, and education. It has members from the Pakistan Agriculture Research Council, Department of Plant Protection, Environmental Protection Agency and institutional biosafety committees. The functions of the committee have been elaborated in detail leaving no ambiguity at any level. The Technical Advisory Committee functions under the NBC, headed by the Environmental Protection Agency Director General, with representation from all the concerned segments. It augments the tasks dedicated to the NBC. Currently, astounding efforts are directed towards the formulation of institutional biosafety committees to be functional at the pertinent levels. The focal intention is to make these committees more task-oriented. They are to be chaired by the head of the institution, with members comprising primarily experts and social scientists, and possibly economists and representatives from civil society.

The impact of all these efforts has to be carefully measured thus rendering the system instrumental. The best way to evaluate the impact is through continuous surveillance and auditing, followed by feedback and certification. Dedicated teams are to be responsible for these precise tasks. We are in the process of developing university curricula for biosafety and biosecurity for the concerned specialties. The institutional biosafety committees and experts in the field are being encouraged to participate actively and make concrete efforts for finalization of a detailed standard curriculum.

The approach has been mainly strengthened by the response from the concerned personnel. There is no scarcity of experts in diagnostics and research fields in the country. The aim has been directed at equipping them with biosafety skills, and it is through their dedication that we are targeting and accomplishing our objectives. Presently, there are resilient efforts to bring various groups and agencies to a single platform and receive recognition from the authorities. This is evident from the affirmative response received from the government ministries of foreign affairs, environment, health, and industry. The efforts can further be strengthened by collaboration with the regional associations and endorsement by

international authorities, such as the American Biological Safety Association and the European Biosafety Association. The process of cooperation has already been initiated with regional as well as international agencies.

NATIONAL CORE GROUP IN LIFE SCIENCES

The Higher Education Commission of Pakistan realizes the importance of the life sciences and has launched the National Core Group in Life Sciences (NCGLS) for professionals. This elite group comprises six disciplines: biochemistry, bioinformatics, botany, genetic and molecular biology, microbiology and zoology. Its main objectives include: the promotion of teaching and research in the life sciences in Pakistan; the identification of areas which have direct impact on the economy and interests of the country; preparation of the major projects; and human resource development in the life sciences. The NCGLS has established four resource centres at various universities and imparted training in various advanced biological techniques through national and international workshops, seminars and conferences. Considering the discernment, the group has also been entrusted the job to prioritize the matters related to biosafety and biosecurity.

NATIONAL COMMISSION ON BIOTECHNOLOGY

The National Commission on Biotechnology (NCB) was established in 2001. The basic tasks assigned to the Commission include: human resource development; strengthening research facilities at the provincial level; funding high priority projects for young researchers; establishing a centre for bioinformatics; strengthening the government-private sector collaboration; and promoting research on quality exports. The NCB has been actively engaged in publications and media awareness, and various manuals covering different codes are available for scientists. A comprehensive Pakistan National Policy and Action Plan on biotechnology were introduced in 2003. The overall net effect culminates in strengthening the research, along with strict vigilance on matters pertaining to biosafety.

BIOLOGICAL SAFETY ASSOCIATION

The latest formidable step as part of national obligations was the launch of the Biological Safety Association of Pakistan in March 2008. There has been an overwhelming response from scholars, scientists, microbiologists and people from public health across the country. The core aspirations are capacity-building in terms of developing biosafety expertise in the scientific, legal and technical areas, with extensive coverage of the relevant issues, for example, in risk assessment, risk management, laboratory design and certification, surveillance and auditing, among others. Major focus is on: national training on biosafety; GMO applications and implications; BWC implementation; the training of institutional biosafety committee heads; and developing post-graduate and undergraduate curricula. Up until now the hallmark has been the workshops, which have played a pivotal role in raising awareness among scientists as well as students.

CONCLUSION

The indebtedness of all states to the BWC is undeniable, as the concept of biosafety has been thoroughly recognized and exclusively understood across the states parties. The time has come for vigorous pursuance of biosecurity related issues, indeed there were many valuable deliberations in previous BWC meetings. The scope of biosecurity includes defined select agents, utilization of appropriate equipment, legalized transportation, optimal risk management, perfect supervision, utmost oversight and regular review. The content predominantly revolves around safe practices, control lists, authorized access control, personnel surveillance, authorized transportation and proper record maintenance.

The Government of Pakistan, together with an oversight body, is concentrating in earnest on a national plan. For managing the ultimate degree of biosafety and biosecurity, we need to inculcate dedicated culture for continual awareness and training that will lead to the implementation of best practices in the business.

CHAPTER 13

CASE STUDY II: THE CONTROL OF HUMAN PATHOGENS IN CANADA*

Marianne Heisz

BACKGROUND

Canada published the first edition of the national Laboratory Biosafety Guidelines (LBG) in 1990. These guidelines were based upon the World Health Organization (WHO) *Laboratory Biosafety Manual*, to help laboratories realize a common approach for biosafety practices and biological safety on a national basis.

The LBG were to be complied with on a voluntary basis. However, in 1994 the Human Pathogens Importation Regulations (HPIRs) came into effect, requiring anyone importing a risk group 2, 3 or 4 human pathogen or toxin into Canada to comply with the LBG. The HPIRs are not based on specific lists of human pathogens or toxins. The criterion for inclusion is simply that of belonging to risk group 2, 3 or 4 as described in the LBG. As such, it allows for the capturing of newly emerging human pathogens that might not be specified on a list in a law or regulation. The HPIRs also define "human pathogen" to include a toxin, an artificially produced hybrid or mutant micro-organism that contains genetic components of any micro-organism capable of causing human disease, as well as a diagnostic specimen or other material that an importer has reasonable grounds to believe contains a human pathogen.

---

* Reprinted with permission from the Public Health Agency of Canada.

The HPIRs deal with the importation of human pathogens in risk groups 2, 3 or 4, as well as subsequent transfers within Canada of human pathogens in risk groups 3 to 4. As such, a person who has imported a risk group 3 or 4 human pathogen and then wishes to transfer it to another person, must obtain approval from the regulating body—in this case the Public Health Agency of Canada (PHAC). In order for approval to be granted, the regulating body verifies compliance with the LBG of the receiving laboratory prior to the transfer being permitted. Verification of compliance to the LBG is termed "certification".

For facilities wishing to import risk group 2 human pathogens, a self-attestation programme is in place. A checklist detailing all the mandatory requirements for a containment level 2 facility is completed by the facility wishing to import the risk group 2 material. The regulating body may require additional information or material to support the application. This completed checklist, information and material is then reviewed by the regulating body. If upon verification of the submitted information, it appears that the applicant's facilities, equipment and proposals would meet the operational and physical requirements of the LBG, an import permit is granted. No site visits are conducted. However, unlike for risk group 3 and 4 human pathogens, there are no prohibitions under the HPIRs on the subsequent transfer of the imported risk group 2 materials.

For those facilities importing risk group 3 or 4 human pathogens, certification of the facility by a regulatory authority inspector occurs prior to import and prior to the permit being issued. Annual re-certifications are also conducted on facilities importing risk group 3 and 4 materials. The certification process involves submission and review of facility documentation, including architectural plans, ventilation details as well as standard operating procedures. This is then followed by a site visit, where submitted information is verified by an inspector. Additional tests may be done on-site to further verify submitted documentation.

It should be noted that pathogens with the potential to cause disease in animals are regulated by a separate agency in Canada, and as such, facilities working with those pathogens that can cause disease in humans and animals must also comply with acts and regulations administered by that agency, and obtain permits from both federal agencies.

Although the HPIRs put in place mandatory biosafety requirements for those importing human pathogens, other people in Canada working with human pathogens that were acquired from domestic sources were still not covered by any national legislation or regulation. The LBG were still only voluntary for those working with domestically acquired human pathogens. This was a significant gap in the safety and security with respect to human pathogens. Additionally, under the HPIRs there is no requirement for security screening personnel who work with these dangerous pathogens, nor is there a requirement for the maintenance of inventories. In addition, there are no reporting requirements for inadvertent releases of human pathogens, production of regulated materials or laboratory acquired infections.

ADDRESSING THE GAPS

On 29 April 2008 the proposed Human Pathogens and Toxins Act (HPTA) was introduced in Parliament as Bill C-54. The bill was specifically designed to address the gaps discussed above, as well as allowing flexibility for future developments in science. The policy development behind the HPTA had been ongoing for a few years, but a priority was placed on this project with the severe acute respiratory syndrome (SARS) outbreak in Canada in 2003. This outbreak was a significant situation domestically, as Canada had cases within state borders. However, those laboratories that were working with the SARS virus acquired from domestic sources were not captured by the national biosafety requirements of the HPIRs. The HPTA was passed in Parliament on 23 June 2009.

The HPTA, among other aspects, has key components that are specifically relevant in today's climate of biosafety and biosecurity. Significant features include:

- oversight of imported and domestically acquired human pathogens and toxins;
- personnel security clearances for access to prescribed human pathogens or toxins;
- requirements for recording and maintenance of inventories;
- oversight of transfers;

- a requirement for reporting of inadvertent releases or production of human pathogens or toxins, and of laboratory acquired infections; and
- penalties more in line with the seriousness of the offences.

It would be prohibited to knowingly conduct any of a wide range of activities without a licence from the Ministry of Health, including possession, storage, disposal, import and export of all human pathogens in risk groups 2, 3 and 4, as well as a specific list of toxins. It should be noted that risk group 1 pathogens are not within the scope of the HPTA.

The policy approach for the development of the HPTA was from a public health and safety perspective, and certain specific biosecurity issues (such as personnel security screening and clearances) are addressed in the act. The approach was that good biosafety leads to good biosecurity. As such, the majority of the biosecurity issues that laboratories experience are addressed with a very strong biosafety programme. These biosafety measures are captured within the LBG (as well as any subsequent edition) as well as the HPTA.

Another approach that was taken when developing the HPTA was ensuring that human pathogens were included within the scope of the act by inclusion in a risk group category (risk group 2, 3 or 4) instead of strictly naming organisms on a list. This was a continuation of the approach under the HPIRs. There are lists of human pathogens in schedules to the HPTA, but these are not exhaustive lists of the human pathogens that fall into the various risk group categories. The risk group definitions are based on WHO definitions of risk groups. Note, however, that the only toxins within the scope of the HPTA are those that are specifically set out in a list which is a schedule to the act.

OVERVIEW OF THE HPTA

Basic requirements

To be within the scope of the HPTA, a human pathogen must be listed in one of the schedules to the act or fall into the definition of either risk group 2, 3 or 4, whereas a toxin must be listed in a schedule (exhaustive list in

Schedule 1 or in Part 1 of Schedule 5). The HPTA also has a basic safety requirement. Any person (which includes a corporation or organization) who knowingly conducts activities with a human pathogen or toxin has a general duty of care to conduct that activity safely. The prohibitions against knowingly undertaking controlled activities without a licence are found in Section 7. The controlled activities include possession, storage, disposal, import and export of human pathogens in risk groups 2, 3 and 4 or of toxins. There is also an absolute prohibition in Section 8 for the possession of certain human pathogens or toxins. In Canada's case the only pathogen listed here at present is the virus causing smallpox. This is in response to a World Health Assembly resolution stating that work with this risk group 4 pathogen should only be carried out in high-containment biosafety level 4 laboratories in the Russian Federation and the United States.

Reporting

Sections 12–15 of the HPTA include: reporting requirements for inadvertent releases or production of a human pathogen or toxin; reporting of all laboratory acquired infections; and reporting of missing or stolen pathogens.

The reporting of laboratory acquired infections is a very significant biosafety feature. It requires the PHAC to be informed of the event, to assess the information and the circumstances surrounding the laboratory acquired infection, and to take action as necessary or appropriate. The Agency can also then evaluate the event with respect to the LBG. This allows for evidence-based recommendations and requirements for future editions of national biosafety standards and guidelines.

It had been observed by the PHAC that such information in the past was often not reported simply because of the possible negative impacts on a facility. An important feature of the HPTA is the encouragement for reporting, so that the PHAC can continue gathering information for evidence based-decision making. As such, Section 16 clearly stipulates that all information submitted under Sections 12–15 by a licence holder or a person conducting activities under a licence cannot be used against that person in criminal proceedings (except if in relation to the provision of false or misleading information).

Licensing

Section 18 provides for the issuance of licences and for conditions of licence. The holder of the licence must also inform everybody in the facility what the conditions of the licence are. Licences can be varied, suspended or revoked. The variance, suspension or revocation of a licence can be reviewed by a committee, and this is similar to the existing process under the HPIRs.

Access

The HPTA also has specific provisions for access which require that lists of people who have authorized access to facilities be maintained. An additional feature is that those who do have access to a prescribed set of human pathogens or toxins have valid security clearances. The specific security clearing requirements will need to be specified in regulations. Authorized access for visitors is also indicated.

Biological safety officer

A significant feature of the HPTA for people working with human pathogens and toxins is the requirement to designate a biological safety officer. However, the details of the qualifications, powers and duties need to be specified in regulations.

Exemptions

Exemptions are also a key feature of the HPTA to minimize instances of overlap and duplication with other federal legislation, as well as recognize where there is little or no biosafety risk that must be covered by the HPTA. One exemption in particular is for people who collect samples for the purpose of laboratory analysis or diagnostic testing. This allows individuals who collect samples in the field or in places like blood collection facilities to be exempt from having to obtain a licence under the HPTA.

Inspectors, offences, penalties and implementation

To fully promote compliance, the HPTA provides for the designation of inspectors and sets out their powers. Enforcement is supported by a robust offences and punishment section, where the penalties for offences are

now more in line with the seriousness of the infraction or contravention and the gravity of the potential consequences to public health and safety.

Phased approach

The intention is to have a phased approach to implementing the HPTA. Initial provisions that came into force upon passage of the act include the requirement to provide basic reporting information, the obligation to take all reasonable precautions, the inspection provisions, and the prohibition against intentional release of human pathogens or toxins causing a risk to the health or safety of the public. The second phase will include extensive consultations with stakeholders to develop the programme and regulatory framework. The third phase will be to bring into force the remainder of the HPTA and the new regulations. The HPIRs would most likely stay in force until the HPTA is brought fully into force.

ADDENDUM

Bill C-54 died on the order paper when a federal election was called on 7 September 2008. The proposed HPTA was then re-introduced in Parliament on 9 February 2009 as Bill C-11 and after significant debate and analysis, the bill became law on 23 June 2009.

Over the coming years Canada will be conducting nation-wide consultations to inform the policy and regulatory development of the full programme under the HPTA. As required by the Cabinet Directive on Streamlining Regulation, these consultations must be comprehensive and meaningful and, as such, will greatly inform how the biosafety and biosecurity programme under the HPTA will take shape in the form of regulations and other policy instruments.[1]

CHAPTER 14

VIEWS FROM THE FIELD: BIOSAFETY AND BIOSECURITY CHALLENGES IN THE ASIA–PACIFIC REGION

Teck Mean Chua

The Asia–Pacific Biosafety Association (A–PBA) was founded in 2005 with the objective of promoting biosafety and biosecurity in the Asia–Pacific region.[1] It is a not-for-profit professional organization that aims to provide a forum for all biosafety practitioners in the region to share their experiences and knowledge in biosafety and biosecurity. A key goal of the A–PBA is to foster the growth of a regional biosafety community to share a collective responsibility towards better biosafety and biosecurity, as no single state can be effective in its programme against any emergency response to any kind of outbreak of diseases if the neighbouring states are ill prepared. The A–PBA sees biosafety and biosecurity as addressing a collective risk. Given that all states confront the same risk, we all share a responsibility to manage it effectively. This requires us to work together to prevent accidents and incidents. The A–PBA was established to foster such collective action in the Asia–Pacific region.

As the regional forum for biosafety and biosecurity, the A–PBA works through and draws upon the efforts of the national associations. It has a long-standing history of cooperation with the Japanese Biosafety Association and the Korean Biological Safety Association. Recent years have seen several new associations being formed in our region. For example, the Biosafety and Biosecurity Network (Thailand) was formed in early 2008 following a meeting held by the A–PBA in Bangkok. There is now also the Biological Safety Association of Pakistan and the Philippine Biosafety and Biosecurity Association, with both of which the A–PBA has been in communication. The A–PBA has also worked closely with the Biosafety Association for Central Asia and the Caucasus. It is clear that our efforts to foster recognition of biological safety as a distinct scientific discipline are proving successful, and that there is growing interest and

demand in the region for a forum for the dissemination and continued exchange of information on biosafety and biosecurity.

PROMOTING THE SAFE AND SECURE MANAGEMENT OF BIOLOGICAL RESOURCES AND PROCESSES

The A–PBA uses a range of approaches and activities to further its objectives. The centrepiece of the association's efforts is the regional biosafety conferences. They provide a focal point for ongoing activities, gather together expertise from the region and provide a unique setting to share experiences. The conferences rotate from one country in the region to another to generate greater buy in. They also help to build capacity as any resources left over after the conference is used as a seed fund to assist the host in developing its own national biosafety association.

The most recent conference took place in Seoul, the Republic of Korea, in May 2010 and focused on advancing biosafety technology and national legislation in the Asia–Pacific region. Participation was drawn from both the private sector and public sector, and included members of regional and national biosafety associations from around the world. The conference covered: national regulations and legislation in the region; advances in biocontainment technology; international and regional partnership and collaboration; biorisk management and accreditation; dual-use research; as well as applied biosafety. A member of the Implementation Support Unit (ISU) attended the conference and delivered a presentation on the Biological Weapons Convention (BWC).

The A–PBA organizes topic-specific training courses. For example, in January 2011 the Association ran a biosafety management training course in Singapore. It also supports online training and distance learning by facilitating participation in relevant courses, such as the interactive online training course on packaging and shipping of materials offered by the National Laboratory Training Network.

The A–PBA publishes a newsletter, which, in addition to helping to build a greater sense of community and keeping our members up to date with news and events, provides a valuable medium to share technical information on approaches and practices. For example, the August 2010 newsletter provided suggestions on the placement of biosafety cabinets.[2]

The A–PBA also represents on the global stage the views and expertise of biosafety specialists from the Asia–Pacific region. For example, the A–PBA has been an active participant in international standard setting exercises, such as the European Committee for Standardization (CEN) Laboratory Biorisk Management Standard (CEN Workshop Agreement 15793), the development of associated guidance (CEN Workshop 55) and a standard for Biosafety Professional Competency (CEN Workshop 53). It has also participated in the BWC Meeting of Experts. Proposals made by the A–PBA at the 2008 meetings were included in official documents of the process and fed directly into the development of common understandings on biosafety and biosecurity contained in the report of the 2008 Meeting of States Parties.[3]

BIOSAFETY AND BIOSECURITY AROUND THE WORLD

If we look around the world today, we see that the issues of biosafety and biosecurity have evolved differently in different countries and for different regions. In developed countries biosafety and biosecurity are sufficiently well established that concerns have shifted from having to focus almost exclusively on the day-to-day operational aspects to a debate over the possible need for regulation and controls of scientific activities that have the potential for abuse or misuse.

In developing countries the focus remains primarily on the fundamentals of biosafety and biosecurity—how to safely and securely manage micro-organisms and the products of biological processes. Shortcomings in capacity, equipment and human resources can pose a weak link in that chain of control against the misuse and abuse of infectious agents to inflict harm. Simply getting core concepts and procedures into the hands of those working with biological agents and processes is a significant challenge. Through its professional activities, the A–PBA is working hard to build human capacity. We are helping to raise awareness, share experiences and best practices and conduct training. The BWC could play a role in raising awareness. Its meetings, documents and the ISU can make a direct contribution. Perhaps—even more importantly—it can push its states parties to foster national and regional biosafety associations and through them help to ensure that those working in facilities around the world are empowered to do so safely and securely.

Many of the facilities handling infectious agents in developing countries were built more than 10 or 20 years ago, with little or limited provision for biosafety and biosecurity in terms of both design and practice. The conditions found in the majority of these facilities remain shocking to those operating in laboratories in developed countries. But they are the reality in most areas of the world. There need to be efforts to improve the quality of facilities in which our members work. The BWC could play an important role in building such capacity.

In many of the younger communities (those just starting to develop a more structured approach) when it comes to biosafety and biosecurity, there are so many questions. They often receive different answers, which do not always agree with each other. Sometimes this can lead to a lot of confusion. There is still a great deal of work that needs to be done to harmonize and simplify messages. If you look at the documentation made available over the last five years on biosafety and biosecurity, there is no shortage of excellent papers and data to support a good programme to promote biosafety and biosecurity. The challenge comes from the implementation of these programmes, as there are limited resources and infrastructure to support and implement them in a systematic and sustainable fashion. The next step forward is to identify and establish partners and channels that can assist in the implementation of these programmes. There may be a role for the BWC here too.

The A–PBA sees itself as a partner in all these initiatives. The A–PBA stands ready to support all the activities of other bodies such as the BWC or the World Health Organization in enhancing biosafety and biosecurity in our region as well as around the globe. As infectious agents have no respect for boundaries, nationality or morality, the earth is but one country, and mankind its citizens when it comes to the fight against any outbreak of disease or abuse of infectious agents to inflict harm.

SECTION C

OVERSIGHT OF SCIENCE, EDUCATION AND OUTREACH

CHAPTER 15

EDUCATION, AWARENESS-RAISING AND CODES OF CONDUCT

Working paper submitted by Japan to the 2008 Meeting of Experts[1]

While biotechnology has brought enormous benefits to humanity, there are growing concerns about its potential use for purposes prohibited by the Biological Weapons Convention (BWC) due to the dual-use nature of this technology. Against this backdrop and as a way to prevent the misuse of biotechnology, the three topics of education, awareness-raising and codes of conduct were discussed at the BWC Meeting of Experts in August 2008. This section provides an overview of the discussions held at the meeting.

This chapter reproduces a working paper submitted by Japan in consultation with Australia, Canada, the Republic of Korea, Switzerland, Norway and New Zealand (JACKSNNZ) and introduces many of themes that are explored in more depth in the following chapters. The JACKSNNZ is an informal group of states that shares similar views on issues related to biological weapons and the implementation of the BWC. It has been working together since the 2006 Review Conference to promote the strengthening of the convention. As this working paper is a product of close consultations among all seven states, it cannot be altered without consulting all of them, thus the working paper is reproduced here as it was submitted.

This working paper starts by examining the dual-use aspects of biotechnology. It focuses on the need for striking a balance between securing scientific developments and preventing the misuse of biotechnology. The three topics in the title of this chapter (as well as scientific oversight) are discussed as a means for preventing the misuse of biotechnology. For each topic this working paper examines significance and effect, as well as what is needed to enhance efficiency.[2]

*
* *

I. Introduction

1. There is no doubt that advances in biotechnology in recent years have brought about tremendous benefits in medical care, pharmaceuticals, agriculture, food processing, the chemical industry and environmental protection. On the other hand, however, the dual-use aspects of advanced biotechnologies—in which accident or design could lead to the development of biological weapons or harmful pathogens—cannot be overlooked. Given the reality today that relevant information may be found on the internet related to sophisticated technology, it has also become increasingly necessary to pay attention to these risks associated with the dual-use aspects of biotechnology in order to prevent the misuse of biotechnology.

2. Considering the dual-use aspects of biotechnology, even well-intentioned research could bring about harmful results through its misuse. We recognize that with awareness and appropriate guidance, scientists can apply their own expertise to judge the wider ramifications of their research and other activities. Safeguards policies and oversight mechanisms that require all scientists to take responsibility for biosafety/biosecurity should be promoted. At the same time, however, we do not consider it to be effective, efficient or equitable to place the burden of responsibility for any harmful events that may transpire solely on well-intentioned scientists. All relevant actors must be mindful of their responsibilities. In order to prevent the misuse of biotechnology, it is necessary to examine appropriate measures involving not only the scientists, who are obviously the principal actors, but also all other stakeholders, including the policy-makers, regulators, administrators of universities and research institutions, together with academic associations and the private sector.

II. Three effective means for the prevention of the misuse of biotechnology

A. Oversight/Management and control

Significance and effect

3. Although oversight is an effective way for preventing misuse, if it is implemented in an ill-conceived manner, scientific development can be unduly hindered. It is important to institute an oversight mechanism which is meaningful and does not create unnecessary burden. This is essential to make it acceptable for scientists and to forge ownership.

4. As far as is practicable, research institutions and associations that are associated with the work of the life sciences should have appropriate oversight mechanisms.

5. In any event, life scientists themselves need to be actively involved in constructing and instituting such oversight mechanisms in order to make it effective. Therefore, it is desirable to develop a program for education and awareness raising swiftly, which is set out in the below (2).

Points to be examined

Scope

6. Within the scope of oversight, the following elements need to be included: appropriate management of personnel, appropriate management of pathogens and toxins; appropriate management of sensitive information and knowledge about research information and research outcomes; research funding; and the modalities of governance over research programs in universities, research institutions and academic associations.

Oversight of pathogens & toxins and oversight of information & knowledge

7. It is mainly life scientists who may be required in the course of their work to handle pathogens and toxins, and since these biological agents could be also directly used maliciously, it is necessary to institute a legally-binding oversight mechanism over these agents. On the other hand, with regard to

the management of research information, knowledge and outcomes, there is a concern that a similar legally-binding oversight mechanism may not be appropriate since such measures could obstruct scientific development.

8. In shaping an oversight mechanism for research information, knowledge, and outcomes, including the modality of communicating research results, it is considered as essential to involve all relevant stakeholders including scientists and administrators in universities, research institutions and companies, as well as stakeholders in government and the media when appropriate. In this regard, it is also important to study the establishment of a mechanism that enables scientists to consult on their research and to expand the opportunities where the scientific and security communities can communicate with each other.

Research funding and the state of governance

9. It should be encouraged for scientific research institutions to monitor voluntarily, with the help of academic association when necessary, whether research grants are being used for legitimate purposes and whether research projects are properly managed. In this regard, whistleblower systems can be of great importance to support such voluntary monitoring.

B. Education and awareness raising

Significance and effect

10. Programs for education and awareness raising among scientists are a basic means for preventing the misuse of biotechnology.

11. In this light, since these means are different to legally-binding rules or externally imposed norms, they are extremely important in the interest of respecting the autonomous responsibility of scientists without obstructing scientific development. Their role and effect are also significant since they can guide scientists to adopt responsible conduct by themselves voluntarily.

12. Through the efforts to strengthen programs for education and awareness raising, those scientists with advanced technical expertise may take an interest in and provide greater cooperation to not only the oversight of pathogens and toxins, research information, knowledge and outcomes,

but also to the various activities that contribute to the strengthening and thorough implementation of the BWC.

13. The direct effects gained through programs for education and awareness raising may vary depending upon the integrity of the scientific community, which is underpinned by the conscience of individual scientists and their mutual trust. Therefore, from the viewpoint of ensuring the effectiveness of such programs, it is necessary to reflect and institutionalize the outcomes of these programs in an oversight mechanism and the contents of codes of conduct.

Points to be examined

Content

14. In developing the content of programs for education and awareness raising, it is important to deal with the following subjects: ethical and moral principles; awareness of the dual-use risks of biotechnology; management of sensitive research information, knowledge and outcomes; and legal obligations under the relevant treaties and associated domestic legislation.

Targets of education

15. Targets of education must include students (both in universities and secondary schools), researchers at universities, research institutions and private companies, health care workers, etc., who are/will be involved in science now and in the future. It would be also important to include the managers and administrators of universities, research institutions and private companies.

Education practitioners

16. Since the effectiveness of educational programs can be significantly influenced by the quality of the education practitioners, it is essential to secure personnel with appropriate qualifications. In this light, it is also important to examine what qualifications are required and how to train personnel as education practitioners.

Educational material

17. Since the content of education should cover many topics, it is necessary to include not only the views of scientists but also the views of other relevant stakeholders.

18. In this regard, even though the development of educational programs at the government level has not seen great progress, joint research to develop an educational module for life scientists has been underway between the University of Bradford of the United Kingdom and the National Defense Medical College of Japan. Their joint research is expected to generate important outcomes.

C. Codes of Conduct for Scientists

Significance and effects

19. Codes of conduct can serve as a guideline for scientists to prevent the misuse of biotechnology, and are expected to play a unique role since they confer greater respect to the autonomy of scientists than oversight mechanisms. In order to make codes of conduct effective, it is important when formulating and propagating codes to emphasize the positive impact of "protecting legitimate research activities of well-intentioned scientists".

20. It is viewed of great significance to encourage the participation of as many scientists as possible in the process of drafting codes of conduct so that they will share and enhance awareness of the issues mutually through discussions.

Points to be examined

Content

21. The contents of codes of conduct cannot be established independently of oversight mechanisms and programs for education and awareness raising, but rather need to be closely associated with the latter two means. When formulating codes of conduct, it is important to emphasize in particular the necessity of incorporating skillfully the two aspects of improving the awareness of scientists and establishing procedures and

rules for the management and control of pathogens and toxins, as well as sensitive research information, knowledge and outcomes.

22. Inevitably, the activities of scientists are likely to be covered by several "layers" of codes of conduct representing various national, institutional, professional and other stakeholder communities. These codes will complement rather than compete with each other. We consider it desirable that stakeholders be encouraged to develop their own codes, applicable to their own circumstances, and articulated to their own audiences.

Universality

23. A variety of rules and regulations related to codes of conduct for life scientists already exist, and the contents of these codes vary among countries and organizations. Therefore, it would be difficult to develop an over-arching "universal code of conduct" concerning all activities outlined by the BWC. Alternatively, forming a common understanding among the States Parties on the important elements of codes of conduct may be more effective.

III. Conclusion

24. Oversight, programs for education and awareness raising and codes of conduct are all effective means to prevent the misuse of biotechnology. Yet, as it has been made evident in this working paper, the significance and effects of each measure are mutually different. Accordingly, by grasping the unique characters and combining them all together in a well-balanced manner, it is expected that all these means can mutually complement one another and produce synergistic effects.

25. Bearing this in mind, it is important to examine how to apply and implement these means appropriately through national and international cooperation and coordination, in order not to hinder the development of science and technology, which have become a vital part of our lives, but to protect the scientific activities of well-intentioned scientists.

CHAPTER 16

CASE STUDY I: THE AUM SHINRIKYO'S BIOLOGICAL WEAPONS TERRORISM IN JAPAN

Katsuhisa Furukawa[1]

The Aum Shinrikyo, an obscure cult religious group, attacked the Tokyo subways, employing sarin gas in March 1995, killing 13 people and injuring 6,273. It remains an empirical example of a religiously motivated cult with an affluent amount of financial and human resources and motivation to use weapons of mass destruction (WMD) against civilians. Aum was founded in the mid-1980s by Chizuo Matsumoto (also known as Shoko Asahara). From the onset Asahara was obsessed with Armageddon and conspiracy theories, and had expressed his concern and interest in WMD since the mid-1980s. He believed a shadowy organization controlled the world, and only Aum could save it. As Aum grew, Asahara desired to take over the government. In 1990 Aum ran in the national election but lost miserably. Hence, in order to "salvage" the contaminated souls of humankind, Asahara believed they had to kill mankind. Aum examined various WMD programmes, including biological, chemical, nuclear and plasma weapons. This chapter provides an overview of Aum's biological weapons terrorism and lessons for preventing future terrorism of this kind.

AUM'S BIOLOGICAL WEAPONS PROGRAMMES

In 1990 Asahara ordered his followers to cultivate the bacterium *Clostridium botulinum* for aerial dispersal. The idea was to disperse a massive amount of *C. botulinum* in Tokyo, and throughout the world by the prevailing westerlies.[2] However, there was confusion within Aum over the distinction between *C. botulinum* and botulinum neurotoxin, indicating their lack of understanding. They collected soil in Hokkaido Prefecture believed to contain *C. botulinum*. They also procured horses in order to produce serum.[3] However, the programme suffered many setbacks. First,

they failed to isolate the *C. botulinum* from the soil—or perhaps it was not in the soil from the beginning. Even an inoculum could not be prepared. Construction of a cultivation device also failed, contaminated by the bacterium *straphylococcus saprophyticus*.[4]

Even so, in around April or May of 1990, pressed by Asahara, Aum members supposedly dispersed *C. botulinum* in areas near the Japanese Diet, the Imperial Palace, the US Embassy in Tokyo, the US military base in Yokosuka, the Kasumigaseki area in Tokyo (where the government headquarters are), as well as a river that led to a filtration plant. A jet-spray device on car was used but proved faulty, resulting in the failure of the plots.

In 1992 Aum started an anthrax programme. Scientist obtained a culture of *Bacillus anthracis* from one Aum member engaged in medical research. From 29–30 June 1993 Aum dispersed a liquid suspension of *B. anthracis* from the top of its Tokyo headquarters in an attempt to cause an inhalational anthrax epidemic.[5] Later scientific analysis determined that it was *B. anthracis Sterne*—an attenuated strain of *B. anthracis* used to vaccinate animals against anthrax. The use of an attenuated strain of *B. anthracis*, low spore concentrations, ineffective dispersal, a clogged spray device, and inactivation of the spores by sunlight were all likely contributing factors to the lack of confirmed human cases. Asahara indicated that this was an experiment to simulate how materials in a mist form might disperse in the air.[6]

They even conspired to disperse *B. anthracis* at the wedding ceremony of Imperial Crown Prince in June 1993, but abandoned the plot due to a lack of preparation time. Around August 1993 they tried to disperse *B. anthracis* near the Imperial Palace in Tokyo, but the dispersal devise malfunctioned. A repeat near the facility of another religious organization in Tokyo in November also failed. There is evidence that similar attempts were also made in Yokohama city and the Kasumigaseki area. However, since no harm was done, nobody was charged.

The anthrax programme continued at Aum's headquarters, near Mount Fuji. Aum's biological weapons laboratory was designed for P-2 level experimentation. However, this programme also failed. In May 1994 Seiichi Endo, one of Aum's biological weapons programme leaders,

presented what he explained as incubated culture of *Shigella* and *C. botulinum*, although this claim has not been confirmed.

Lastly, on 15 March 1995 (five days before the Tokyo sarin attacks), Aum attempted to launch a botulinum attack on the police. Three attaché cases were found in Kasumigaseki subway station, near the exit close to the headquarters of the National Police Agency of Japan. Inside each attaché case was an elaborate vaporizer with bottles of liquid, resembling a humidifier. Aum meant to disperse an aerolized form of *C. botulinum* to kill police officers. Liquid containing *C. botulinum* in the container was to be vaporized by the ultrasonic oscillation board located at the bottom. Commercially available ventilation fans were used. However, the bottles were filled with a harmless liquid. Endo could not prepare botulinum toxin in time.

Aum also tried to produce an anthrax vaccine and a vaccine or serum for bacteria botulinum or botulinum toxin.[7] However, these products apparently seemed defect. Soon after injecting, one senior Aum member felt very chilly, began vomiting badly, and slept (or became unconscious) for a few days. Nakagawa himself also suffered from an acute allergic response when he injected himself with the serum taken from a horse against botulinum toxin.[8] In short, the quality of Aum's medical countermeasures seemed very poor. There have also been vague media reports about Aum's interests in *Coxiella burnetii* and the Ebola virus, but they have not been confirmed.

Aum's biological weapons programmes all failed, and no harm was done at all. Their activities were badly planned and ill-prepared. When planning the WMD, Asahara asked a small number of those close to him for advice. Technical feasibility was barely considered, nor was a thorough strategic examination made. The programmes were led by Seiichi Endo and Tomomasa Nakagawa—both unreliable managers. Endo was a failed scientist and Nakagawa suffered from dissociative identity disorder.

Endo studied at a veterinarian school, where he studied molecular biology. He also studied genetic engineering, with work as prions as his research subject. Later, in 1986, Endo moved to the research institute of virology of one of the most respected Japanese universities, where he studied genetic analysis of adult T-cell leukemia virus and the human immunodeficiency virus (HIV). He also studied toxins. However, his research did not go

well, and he came to feel that genes did not constitute the essence of life and modern science did not have all the answers. Eventually, he became drawn to religious views of life. Endo claims that after reading one of Asahara's books, Asahara appeared in his dream and poured spiritual energy into Endo's body. He even claims he saw golden light when just holding Asahara's book and had an out-of-body experience. Endo became convinced that there was another world. In the fourth year of his doctoral degree programme, Endo moved into the Aum Shinrikyo.

During childhood, Nakagawa admired Black Jack, a main character in a famous Japanese cartoon. Black Jack is an illegal doctor without official certification but has magical powers to conduct any difficult surgery successfully and cure most patients. Nakagawa aspired to become a doctor like him. Nakagawa continually went through various mysterious experiences. He told his friends and professor about these experiences but no one believed him, resulting in feelings of loneliness. After graduating in medicine, he worked as a physician in a hospital. However, he was soon disappointed by his senior physicians, who seemed—in Nakagawa's eyes—as if not to care about their patients' deaths. He continued to have various mysterious experiences. A believer in reincarnation, he often dreamed visions of his previous lives. "As I went through special experiences after I met Asahara in April 1988, I thought that there was another world different from this life. My view of life changed, and I felt that I could not live without this religious organization".[9] At that time, however, Nakagawa also described his condition as having been in a constant "panic" constantly. His friend observed that for Nakagawa, "an abnormal condition with mysterious experiences was his normality".[10] A psychiatrist testified later that Nakagawa's symptom was typical of "shaman disease", a form of dissociative identity disorder.[11]

LESSONS FOR THE FUTURE

Asahara and his scientists referred to biological weapons in speech and publications. When a cult or violent, extremist organization begins to talk about specific types of weapons, the government may be better advised to take them seriously.

As the Aum advanced their biological weapons programmes, their messages began to become violent. Many cults or violent, extremist

organizations need an external enemy in order to solidify internal cohesion. They try to invoke the fear among their members that they are under attack from outside. Here world super powers are often described as the primary enemy. The level of the organization's obsession with super-power conspiracy theories could be one indicator about the organization's obsession with violence. It is better to seriously analyse the context under which the conspiracy theory is conveyed to the members within such organizations.

Management of the "dual-use risks" of science and technology is important. Science and technology can be used for both good and malicious purposes. Aum legally procured various equipment for WMD programmes from commercial companies. Aum received WMD-related information (mostly unclassified) from abroad. Unclassified information contributed to help Aum scientists advance their understanding. The risk of diversion of dual-use hardware, technologies and knowledge to illicit non-state actors and states needs to be minimized. Caution is also needed when publishing sensitive information. Aum scientists examined widely available literature to deepen their understanding.

It is necessary to develop both regulatory and voluntary measures. Better governance structures are needed within the academic and scientific community. Close cooperation among intelligence agencies, law enforcement, national security and scientific communities is also essential. Tools such as intellectual property rights or ethics in science (such as codes of conduct) could strengthen non-proliferation of dual-use assets.

Aum recruited talented young scientists from the best universities in Japan. The Aum Shinrikyo's leaders included people from various backgrounds. Within Aum 40 members were engaged in producing biological and chemical weapons. Of those, 25 were prosecuted. Among Aum's full-time priests at least eight came from graduate schools of pharmacy, science and technology, or agricultural research. Another 107 of them had studied medical science, pharmacy, science and technology, or agricultural studies in undergraduate schools.[12]

These scientists became detached from reality. They had a relatively low expectation of the future. One scientist studied at a top-class research programme, but was disappointed by the research environment. He was not allowed to conduct any innovative research. Another scientist felt

emptiness because any scientific research could soon become obsolete. He looked for something absolute, everlasting—like religion. Other scientists enjoyed research at Aum. Aum's chief chemist later said during the police investigation, "I was able to do whatever research I wanted in Aum. It was a fantastic place".[13] Academic and scientific institutions should constantly strive to enhance their attractiveness of innovative environment for young scientists.

Once Endo predicted that genetic engineering technologies would be used for future biological weapons. He argued that "an unknown life-form incorporating various genes will be used as new biological weapons".[14] This remark indicated his interest in inventing new biological weapons using genetic engineering. The international community should be reminded of this challenge.

CHAPTER 17

CASE STUDY II: AN AUSTRALIAN PERSPECTIVE ON AWARENESS-RAISING, EDUCATION AND CODES OF CONDUCT

Robert Mathews

Under Article IV of the Biological Weapons Convention (BWC), each state party is required, in accordance with its constitutional processes, to take the necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention or transfer of biological weapons. This, in effect, means that each state party is required to enact penal legislation to prohibit and prevent any activity in breach of the convention conducted within its territory, under its jurisdiction or anywhere under its control.[1]

It was recognized early in the life of the convention that passing domestic legislation and regulations is not sufficient in itself to ensure effective national implementation. The various domestic laws and regulations of biological activities flowing from the international obligations under the BWC clearly have an impact on the biological science and technology communities, meaning that effective domestic implementation of the convention will require awareness of the BWC obligations and associated domestic laws and regulations within the relevant scientific communities. Hence, the Second Review Conference, in 1986, noted the importance of "inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol".[2] But despite similar declarations being agreed by the Third and Fourth Review Conferences, in 1991 and 1996, the awareness of the provisions of the BWC and the domestic law flowing from the BWC among the scientific communities has remained low.[3]

However, the events of 11 September 2001 and the anthrax letters later in the same year led to greater recognition that if all states parties to the BWC

fully comply with their national implementation obligations under the convention, this would substantially raise the barriers to the proliferation of biological weapons (including improvised devices containing biological agents by a terrorist group or biocriminal).[4] Furthermore, major advances in biological sciences[5] and the increasing globalization of biological sciences and biotechnology since the latter part of the twentieth century have led to the:

- possibility of inadvertent assistance of the scientific community to bioterrorism and biological weapons proliferation;
- possibility of a biological weapons programme being obscured within industry; and
- possibility that "cutting edge" research being undertaken in universities and other research institutions may result in new knowledge that may lead to more effective biological weapons (sometimes referred to as "experiments of concern").[6]

These developments led to the decision at the reconvened Fifth Review Conference, held in Geneva, in November 2002, to conduct a three-year intersessional programme of work to consider various topics designed to strengthen the national implementation of the BWC, which included an increased awareness of BWC-related issues through the development, promulgation and adoption of codes of conduct for scientists.[7] The Sixth BWC Review Conference, held in Geneva, in November 2006, agreed to continue this intersessional programme of work, with one of the topics for 2008 being "Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention".[8]

This chapter continues with the consideration of the important roles for codes of conduct in facilitating and supporting BWC-related awareness-raising, and then discusses the various activities that are being undertaken in raising awareness of the convention and related legislation and regulations among relevant scientific communities in Australia.

THE ROLES OF CODES OF CONDUCT IN SUPPORTING AWARENESS-RAISING

The various issues associated with codes of conduct in support of the objectives of the BWC were considered during our preparations for the BWC regional workshop held in Melbourne in 2005. At the outset we recognized the important role of codes of conduct in facilitating the development of a responsible culture and behaviour in individual scientists in workplaces, and that the development of appropriate workplace regulations and oversight processes would minimize the risk of misuse of biological sciences for hostile purposes.[9] We came to the view that a major role of codes of conduct is to raise awareness of BWC issues, including:

- international obligations under the BWC;
- BWC-related domestic laws and regulations;
- dual-use dilemma (including "experiments of concern"); and
- possibility of a well-intentioned scientist inadvertently assisting or supporting either the proliferation of biological weapons or bioterrorism activities.

It was also recognized that codes of conduct would serve to assist practitioners to apply sound judgment in assessing the impact of their activities on broader ethical, safety and security issues.

During the 2005 Meeting of Experts we suggested that it may be useful to think of codes of conduct as occurring in a number of layers, including:

- a universal code;[10]
- codes developed by scientific societies;[11] and
- codes developed by workplaces (or institutional codes).[12]

The various layers of codes (universal, scientific society and workplace) were recognized as complementary and mutually reinforcing, and would be most effective as a package.

The original objective of the 2005 topic was the development of a new code of conduct. However, it soon became apparent—based on our

discussions with representatives from a number of scientific societies and workplaces—that in many situations there was a preference to add BWC-related elements to an existing code, rather than develop a new code specific to BWC issues. For example, Australia's Biotechnology Organisation (AusBiotech) has its Code of Conduct, which includes the following element:

> Opposing the use of biotechnology to develop or produce any biological or other weapons.[13]

The Australian Society for Microbiology (ASM) has its Code of Ethics,[14] which includes the following element:

> The Society requires each member not to engage knowingly in research for the production, or promotion of biological warfare agents.[15]

We subsequently prepared drafting elements that could be used as a starting point in either the development of a new workplace code or be added to an existing code.[16]

Following the intersessional BWC meetings in 2005, there have been several initiatives by international governmental agencies, professional organizations and associations, and academic institutions to provide guidance in the development of BWC-relevant codes of conduct.[17] The intersessional meeting in 2008 recognized that such codes can complement national legislation, regulatory and oversight frameworks and help guide science so that it is not misused for prohibited purposes. As with the other topics covered in the BWC intersessional programme of work, participants recognized that no one size fits all, and that the best approach may be a range of regional, national, societal and workplace codes.[18]

OUTREACH AND AWARENESS-RAISING

The challenges

Historically, there have been a number of educational courses covering various aspects of the BWC. However, these courses have been mainly provided in postgraduate international law, arms control or international security studies, or in military law courses. There have been very limited

efforts by educational institutions to provide courses to enable life science students to become aware of the obligations under the BWC (and more recently the obligations and requirements under the biological component of Security Council resolution 1540).[19]

Similarly, there have been limited efforts in the past by governments to ensure that the scientific communities working with pathogens and toxins are aware of the obligations under the BWC and resolution 1540, as well as the domestic laws and regulations which flow from these international obligations.[20] There have also been limited efforts by the managers of biological facilities to ensure that the scientists there working with pathogens and toxins are aware of the convention's obligations and the domestic laws and regulations.[21]

At the Meeting of Experts in 2005 we reported that among the Australian scientific community there is a low level of awareness of the risk of misuse of the biological sciences to assist in the development of biological weapons.[22] One problem is that many scientists working in dual-use areas simply do not consider the possibility that their work could inadvertently assist a biological weapons programme. For most of these researchers biological weapons issues may seem irrelevant and therefore strong advocacy is required to overcome natural resistance or ignorance. As discussed previously, it has been recognized that having codes of conduct which incorporate and highlight these issues is an important step in raising awareness.

However, it is not enough simply to put such codes in place. Without effective measures to inform scientists about the existence and importance of such codes, attitudes and awareness will remain largely unchanged. With this in mind, we have explored the promotional issues associated with publicizing various codes, which should form an important element of awareness-raising activities.

For example, we noted that in outreach and awareness-raising activities, aimed at scientists, about the existence of codes of conduct governing their work, one of the major difficulties is the diverse and disparate nature of the scientific community. Scientists work in many fields, from academic research through to clinical pathology laboratories and industry. We need to reach research scientists in many fields, including biologists, chemists, medical and veterinary microbiologists, pharmaceutical

researchers, physicists and toxicologists, who may be working on projects that could be relevant to biological weapons development. Universities, hospitals, government and commercial laboratories, and small and large biotechnology companies will all need to be targeted for effective penetration of the message relevant to a scientific code. Many people working in these industries will be difficult to reach because they will not think of themselves as biological scientists or doing work that could be relevant to biological weapons. Reaching scientists and administrators in diverse fields presents a major challenge and requires a concerted and comprehensive campaign.

A further complication is that the scientific population is a fluid one, with many new people entering the field on a continual basis—as graduate students in research laboratories or new researchers in commercial areas. Therefore, it was recognized that any education campaign has to be a continual process. The information needs to be presented regularly and through multiple channels involving both bottom-up and top-down approaches.

A STRATEGIC APPROACH

It was recognized, given the diverse nature of the scientific population, that targeting high school or secondary school students may constitute an effective method of reaching the whole scientific community with a general message outlining the key issues. Incorporating the message into the school curriculum will provide coverage of a broad cross-section of the community, including those who will one day become scientists dealing with these issues. Such messages could be incorporated into a larger component of the curriculum, covering discussions on ethics and values.

While targeting secondary schools would have clear, long-term benefits, there is also an immediate need to reach those already practising biological sciences and to ensure that early messages are reinforced at every stage of the journey from secondary to tertiary education and into the workplace. In considering ways to achieve this, we examined methods by which other messages have been disseminated effectively to similar audiences. Examples of these include raising awareness of quarantine issues to the Australian public at large, and targeting the biotechnology community to

provide education concerning gene technology regulations. We note that in both cases it took many years to achieve high levels of awareness.

Identifying target audiences will be a key step in raising awareness of codes of conduct. To assist in the dissemination of information relevant to BWC issues, Australian officials are in the process of undertaking outreach to the following types of institutions:

- professional societies and professional bodies;
- institutional biosafety committees (IBCs), noting that Australia has a comprehensive network of IBCs, established under the Gene Technology Act 2000, for organizations involved in work with genetically modified organisms (GMOs);
- animal experimental ethics committees, human ethics committees and scientific review bodies; and
- direct targeting of institutions, including university vice-chancellors, faculty heads, and the heads of institutions and companies.

The principle of an integrated communications strategy using multiple, credible sources of information should also be used to disseminate a message on codes of conduct to scientists. Possible channels for communication include:

- print media, including scientific journals and newsletters of professional societies;
- public relations activities, including a presence at events such as scientific conferences and industry conventions, distribution of brochures, stickers and posters, as well as poster and oral presentations, and video displays;
- collaborative promotions that encourage companies, professional societies or other relevant bodies to become involved in disseminating the message; and
- weblinks and shared Internet resources, which are a powerful tool in the provision of educational material accessible to teachers in high schools, or safety officers in research and commercial establishments.

An important technique in encouraging widespread awareness is to distil the message into one or a few key concepts that can be transmitted in a few words and in a manner that will attract people's attention. While making available detailed information on any code of conduct is obviously important, a one line statement that encapsulates the key message in an easy to recall format would achieve widespread awareness of the existence of the code and its basic principles.

PROGRESS TO DATE

Australia began outreach and awareness-raising on BWC-related issues in 1990, with a set of guidelines developed by the Department of Foreign Affairs and Trade to raise the awareness of industry and researchers about the risk of inadvertent involvement in the biological weapons programmes of other states. These guidelines have been circulated to the biological industry, universities, relevant professional associations and government agencies.

In more recent years these guidelines have been complemented by more prioritized outreach and awareness-raising activities by government agencies to target those parts of the scientific community which are most directly affected by the BWC and biosecurity-related legislation, as discussed below.

Implementation of the Security Sensitive Biological Agents Regulatory Scheme

The National Health Security Act 2007 (NHS Act) was passed by the Australian Parliament in September 2007.[23] Part 3 of the act establishes a regulatory scheme for biological agents of security concern and establishes a national authority (based in the Department of Health and Ageing) to regulate organizations that handle security sensitive biological agents (SSBAs). The NHS Act establishes a list of SSBAs to be regulated, a national register updated with mandatory reporting, purposes for which the SSBAs may be handled, security (physical, personnel, information management and transport) standards that must be met while handling SSBAs, exemptions from regulation, and an inspection and auditing scheme to monitor compliance with the regulatory scheme. The regulatory scheme in Part 3 of the NHS Act is built around the List of SSBAs, which was

established by the Minister for Health and Ageing in November 2008 and amended in November 2009.

An education and awareness-raising programme has been developed to promote the recognition and understanding of the new SSBA Regulatory Scheme, and to ensure that the regulated community is able to comply with their obligations under the NHS Act, its associated regulations and the SSBA Standards. An education and awareness-raising programme has used a variety of media to communicate with the stakeholders, including surveys of relevant facilities, road shows, workshops, newsletters, a survey and a dedicated website.[24] Briefings on the BWC and associated legislation, including the Crimes (Biological Weapons) Act 1976, are included in the SSBA outreach activities.[25]

Export licensing on BWC-related goods

Australia's Customs Act 1901 and the associated Customs (Prohibited Exports) Regulations 1958 prohibit the exportation of defence and dual-use goods listed in the Defence and Strategic Goods List (DSGL) without prior permission from the Minister for Defence or an authorized person. Applications to export goods listed in the DSGL are considered on a case-by-case basis against published policy criteria to ensure exports of defence and dual-use goods are consistent with Australia's broader national interests and international obligations. Part 2 of the DSGL covers goods with dual-use, which comprise equipment and technologies developed to meet commercial needs but which may be used either as military components or for the development or production of military systems or weapons of mass destruction (WMD). As such, Part 2 includes human pathogens and toxins, animal and plant pathogens and equipment capable of being used to develop biological weapons.

Australia's Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and associated regulations are also administered by the Department of Defence and complement the existing controls contained in the Customs Act 1901 and the Customs (Prohibited Exports) Regulations 1958. The act prohibits the supply or export of goods not otherwise controlled by the Customs Act or the provision of services in circumstances where the goods or services may be used to assist in the development, production, acquisition or stockpiling of WMD, including biological weapons or their delivery systems.

Australia's Defence Export Control Office (DECO), which is responsible for the day-to-day administration of the Customs Act 1901 and Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and their associated regulations, undertakes regular outreach seminars in major Australian cities to provide information on the legislation and regulations covering exports of dual-use biological materials, equipment and technology.[26] DECO also provides a range of publications that provide information on specific areas of export controls.

National Framework for Ethical Principles in Gene Technology

Following the Gene Technology Act 2000, the Gene Technology Ethics Committee (GTEC) was established in 2001 to provide advice on request on ethical issues in relation to GMOs. In 2006 GTEC finalized and published the *National Framework for the Development of Ethical Principles in Gene Technology* to provide a national reference point for ethical considerations that should be taken into account when developing ethical principle relevant to environmental and health issues in gene technology, GMOs and genetically modified products.[27]

The National Framework, which is accessible from the website of the Office of the Gene Technology Regulator,[28] identifies the values and ethical principle that ought to govern work involving gene technology within the context of the Gene Technology Act 2000 and corresponding state and territory legislation. Several of these principles are relevant to the prohibitions outlined by the BWC or strongly complement the objectives of the convention and the promotion of sound biosecurity and biosafety practices. The National Framework can play a role in helping gene technology practitioners determine in a straightforward and non-prescriptive manner how to best carry out their activities without risk of contravening the provisions of the BWC.

Outreach to academia

In 2009 members of Australia's National Centre for Biosecurity (a collaboration of the University of Sydney and the Australian National University) conducted a pilot series of four interactive seminars for Australian scientists and students on the potential security risks of laboratory research on pathogens micro-organisms—including the relevance of the BWC. This series of seminars, funded by the US-based

Alfred P. Sloan Foundation, was based on the programme developed in the United Kingdom by the University of Bradford and the University of Exeter.[29]

Planning future outreach and awareness-raising activities

In recognition of the high levels of cooperation necessary between government officials and the relevant scientific communities to achieve progress in awareness-raising activities, there has been engagement by government officials with a number of Australian universities, as well as the Australian Academy of Science, the National Centre for Biosecurity and relevant scientific societies, to develop a plan to enable more effective outreach activities and practical plans to implement the strategic approach outlined earlier.

CONCLUSION

While the initial expectations of the BWC Intersessional Process in Geneva were generally fairly modest, it has proved to be a significant innovation. With respect to oversight, education and awareness-raising activities, there have been very useful discussions at the meetings in Geneva and at a number of national and regional workshops. As a result, there are now common understandings among those who have participated in the various meetings and workshops of the importance of this set of activities. And the critical link between effective national implementation of the BWC and effective oversight, education and awareness-raising strategies—including the important role of codes of conduct in achieving these objectives—is now better understood.

With respect to promoting effective action, as we have discussed above, awareness-raising in the broad scientific community presents major challenges—and there is no magic wand. A major effort will be required to ensure that all relevant scientific communities are aware of the provisions of the BWC and the potential dual-use aspects of their work, have the necessary codes of conduct enacted, and have developed the necessary culture of responsibility in their workplaces to ensure that they fully comply with all legislative and regulatory provisions from the obligations in the BWC, and do not inadvertently assist in any activity prohibited by the convention.

There are limits to what can be achieved by government officials without high levels of cooperation from the broader scientific community—hence the importance of cooperative efforts between relevant government agencies, and between government and relevant educational, scientific and industrial communities. Clearly for education and awareness-raising to be effective, this cooperation will need to extend to government agencies, scientific societies, educators, scientific researchers and industry representatives who have not traditionally been involved with BWC-related activities.

Awareness-raising clearly needs to be both a "top-down" and "bottom-up" process. In particular, to be effective there need to be "top-end" champions, both within government (ideally high-level decision-makers in key agencies) and in the academic, research in industrial communities (including scientific societies, academies of science and senior executives). There also need to be champions at the "coal face" to develop and promote the various bottom-up activities, including developing and adapting existing workplace codes and ensuring that the message is fully appreciated by the workplace practitioners.

As a final comment, it must be emphasized that the oversight, education, awareness-raising and codes of conduct activities discussed in this chapter will need to be a continual process because of the changing players and changing technologies in the various biological sectors. Clearly a state party cannot simply "do it once" and then put a "tick in the box".

CHAPTER 18

CASE STUDY III: THE DUTCH EXPERIENCE OF A CODE OF CONDUCT ON BIOSECURITY AND FURTHER

Koos van der Bruggen[1]

> There is no technical solution to the problem of biological weapons. It needs an ethical, human and moral solution if it's going to happen at all.
>
> Joshua Lederberg (1925–2008, Nobel Prize for Medicine 1958)

The national Code of Conduct for Biosecurity, directed at universities and research institutes, was published in 2007 by the Royal Netherlands Academy of Arts and Sciences (Koninklijke Nederlandse Akademie van Wetenschappen, KNAW) at the request of the Dutch Ministry of Education, Culture and Science. This request followed on the publication of a statement on biosecurity by the InterAcademy Panel on International Issues (IAP), a global network of science academies.[2] The IAP statement focused on the potential impact of biosciences research on our global society and particularly on the risks associated with the misuse of such research. This statement was published in 2005 and has now been endorsed by 68 academies from all over the world. The statement itself is not a code of conduct, but it formulates five principles that should be taken into account when drafting a code of conduct. These principles are: awareness, safety and security, education and information, accountability and oversight.

WHY A CODE OF CONDUCT?

A code is a set of principles and instructions that are binding on members of a particular group in a profession or industry. Codes should not be

confused with guidelines (which are less binding) and contracts or treaties (which are more binding). Moreover, codes can be classified into different types: aspirational codes, such as codes of ethics, with the aim to alert and set realistic or idealistic standards; educational advisory codes, such as codes of conduct with the aim to provide guidelines, raise awareness or debate and foster moral agents; and enforceable codes, such as codes of practice with the aim to prescribe or proscribe certain acts.[3]

The main aim of the Dutch Code of Conduct for Biosecurity is to be seen as a contribution to awareness-raising. The KNAW saw it as its first task to make an inventory of existing codes of conduct in other states and of existing Dutch and European laws and rules on biosecurity. Questions were asked such as: What is its added value alongside existing codes and legislation at different levels? And will a code of conduct provide this added value or would new or amended legislation be more appropriate? Answering these questions led to the opinion that a code of conduct is a useful—though not the only—instrument in a process of making more people aware of the risk of the dual-use of research results in the life sciences. It is an illusion to think that a code of conduct can prevent the abuse of science in all circumstances. As was said at an international workshop organized by the National Science Advisory Board for Biosecurity (NSABB), "a code of conduct can make good people better, but probably has negligible impact on intentionally malicious behavior".[4] Because of that, it is evident that the government is developing other measures in parallel to prevent the misuse of biological science and, ultimately, to prevent an attack with biological weapons. These measures vary from physical measures, screening, control of import and export of dual-use agents to new legislation. The Dutch National Coordinator for Counterterrorism has also set up task forces to strengthen the security measures of all relevant research institutes in the Netherlands.

INVOLVEMENT OF STAKEHOLDERS

If a code of conduct is to have its intended effect, the content has to link up with relevant scientific, social and political developments, and with the daily practice of scientists and their organizations. For that reason relevant actors from science, industry and government have been involved in the development of the code from the beginning. It was decided to establish a focus group whose members would make comments and suggestions

based on their practical experience as researchers and policymakers. Their participation made the code practice-oriented. Moreover, it was the first step in a process of raising awareness. For most members of the focus group—although familiar with questions of biosafety—the issue of intentional misuse of the life sciences was new. It can be shown that the debates that have led to the Code of Conduct had their own impact on a growing awareness, be it still in a rather small circle of scientists involved. With the help of insights that were developed by the stakeholders, suggestions and ideas were identified and modified for the Code of Conduct.

THE CODE OF CONDUCT

Many people expect the breakthroughs that have been achieved in recent years to make a major contribution to solving health, food and environmental problems. And progress is being made all the time. Research in the fields of genomics and proteomics is still in its infancy. One of the topics of recent debate is synthetic biology, which is the design and replication of biological components, devices and systems and the redesign of existing, natural biological systems (for example, a virus or bacterium) for specific purposes, such as the development of medicines. But—as said before—often people, including scientists and experts in the life sciences, are unaware of the other side of the coin: the possible dual-use (or the results) of scientific research in the life sciences. This is one of the main principles underlying the Code of Conduct: to raise awareness about possible dual-uses of life sciences research.

In line with the aims of a code of conduct, it was decided that it should be a concise document, which should concentrate on the main issues related to dual-use. The code of conduct offers rules for responsibilities and gives suggestions for regulation and sanctions on the following issues: raising awareness, research and publication policy, accountability and oversight, internal and external communication, accessibility, shipment and transport.[5]

Dissemination process

In October 2007 the national Code of Conduct for Biosecurity was presented to the Ministry of Education, Culture and Science. The

minister—after passing the Code of Conduct on to Parliament—asked the KNAW to start a process of dissemination.

The Code of Conduct has been published both in Dutch and English. Hard copies were available during the Meeting of Experts in Geneva, from 18–22 August 2008. Both language versions have also been placed on the KNAW and downloadable versions have been copied to websites of various scientific institutions.

Another way of disseminating the Code of Conduct is by organizing debates and conferences. The KNAW has—together with other parties—organized debates with representatives of industry and research funding organizations. More debates have been scheduled. Moreover, presentations have been and will be given as well as articles published in journals of scientific unions and professional organizations. There is a plan to develop awareness-raising audiovisual materials for students—who are the researchers and scientists of the future.

International aspects

The Dutch Code of Conduct for Biosecurity has been brought to the notice of foreign academies of science and other organizations through the channels of the IAP and at scientific conferences. The Ministry of Education, Culture and Science has spread the Code of Conduct to other governments via bilateral contacts. According to a survey of the academies of science that endorsed the IAP statement, only a very few states have so far started drafting a national code of conduct on biosecurity. Because of that, the Dutch Code of Conduct might be an interesting example for other states to decide whether and how they can develop their own code of conduct.

CONCLUSION

Many institutional contacts have been made with organizations and people at educational and research institutes. As a result, the Code of Conduct has spread among many organizations and has been published on websites.

Has the purpose of the Code of Conduct for Biosecurity—dissemination and awareness—been reached? Disseminating certainly may be called a

success when looking at the distribution of the code. Over 5,000 Dutch codes and over 1,500 copies in English have found their way to an audience, which—it should be remembered—is of course no guarantee that all copies will have been thoroughly studied. Furthermore, only hundreds of people were reached directly in the various workshops and meetings. This direct confrontation with biosecurity issues has led at least to a basic knowledge of biosecurity issues. And that is the first phase of a process of awareness. From the above it may be concluded that certain important steps have been put to more awareness, but the aims have certainly not been fully met. In this context, a number of initiatives remain important. In order to ensure compliance with the Code of Conduct, continued attention is necessary. The following activities and tasks are proposed:

- keep track of relevant developments in the area of biosecurity;
- coordinate publishing information and educational materials, including maintaining a website with current information;
- organize briefings in order to reach more people directly;
- maintain contact with relevant parties in government and society;
- refer to the experts who can advise on the publication of results of potential dual-use life sciences research; and
- conduct periodic evaluations on the awareness and compliance with the code.

CHAPTER 19

VIEWS FROM THE FIELD I: ENCOURAGING RESPONSIBLE STEWARDSHIP OF THE LIFE SCIENCES

Katherine Bowman, Jo Husbands, Ben Rusek and Barbara Schaal

This chapter describes the activities of a group of national and international scientific organizations in response to the growing concerns that rapid and continuing advances in the life sciences, while producing great benefits, may also yield knowledge, tools and techniques that could be misused to support bioterrorism and new or more deadly biological weapons. These activities, which began in the early 2000s, are one more chapter in a long line of efforts by scientific organizations to address the tensions that periodically arise between the culture of scientific openness and efforts to prevent adversaries from taking advantage of developments in science and technology to threaten national or international security. These efforts also reflect a determination to seek ways to achieve both security and the benefits that continued scientific progress offers to global health, the environment and economic welfare. The Intersessional Process of the Biological Weapons Convention (BWC) has provided an invaluable focal point around which many of these activities could be organized.

The focus of the chapter is how these activities relate to one of the topics for 2008: "Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention".[1] Particular attention is given to the work of the National Academy of Sciences (NAS), although many other organizations are engaged as well, and the international scope of this engagement is especially important for the BWC. The work of these organizations in another critical area for the operation and implementation of the BWC—monitoring and analysing trends in science and technology—will be discussed in a forthcoming report.[2]

THE NAS AND ITS ENGAGEMENT WITH BIOSECURITY

The NAS was founded in 1863 under a charter signed by President Abraham Lincoln. In addition to its role as an honorific society to recognize the achievements of distinguished individuals in all branches of science, the NAS charter mandates the institution to "investigate, examine, experiment, and report upon any subject of science or art" whenever called upon to do so by any department of government. To keep pace with the growing roles that science and technology play in public life, the institution eventually expanded to include the National Research Council (NRC) in 1916, the National Academy of Engineering in 1964, and the Institute of Medicine in 1970. Collectively, the four private, non-profit organizations are now known as the National Academies.

Most of the institution's science policy and technical work is conducted by its operating arm, the NRC. The NRC does not receive direct appropriations from the government for its work. Individual projects are funded by federal agencies, foundations, other governmental and private sources, and the institution's endowment. The work is made possible by thousands of the world's top scientists, engineers, and other professionals who volunteer their time, without compensation, to serve on committees and participate in other activities. In a typical year as many as 10,000 volunteers serve on up to 1,000 different committees, generating 200–300 reports.

The National Academies have been active for many years on issues related to science, security and concerns about biological weapons, as well as long engagement with global public health risks from naturally occurring to deliberate use of disease as a weapon.[3] In the 1980s and 1990s much of the work on biological weapons focused on bilateral contacts with other academies, in particular the Russian Academy of Sciences and the Royal Society of the United Kingdom. This work was carried out by the NAS Committee on International Security and Arms Control (CISAC) and its Working Group on Biological Weapons Control, chaired by Nobel laureate Joshua Lederberg.[4]

In the late 1990s the Working Group expanded its focus to determine how the scientific community could contribute to preventing destructive applications of research in biotechnology. This focus reflected increasing concerns in the US policy community about the potential security risks that could arise from continuing advances in research. A meeting organized by

the Working Group in June 2001 led to plans for a study that would review and assess current US practices for the oversight of research with dual-use potential. The National Academies were thus actively planning the study before 11 September 2001, anticipating that the committee would be able to reflect and develop its recommendations in relative peace and quiet. That opportunity disappeared almost immediately. The project, although privately funded, operated from the beginning with intense interest from US government officials, and had a substantial impact on the choices made by the US government with regard to dual-use issues.[5]

The committee's report, *Biotechnology Research in an Age of Terrorism* (also called the Fink Report after the Chair, Gerald Fink), was released in October 2003, and published several months later.[6] Using several recently published studies as examples, the report coined the phrase the "dual use dilemma", which occurs because the "same technologies can be used legitimately for human betterment and misused for bioterrorism". The committee recommended a bottom-up approach to reduce the threat of misuse of life sciences research by mobilizing the scientific community to police itself. However, it also envisioned a role for the federal government analogous to that played by the Recombinant DNA Advisory Committee of the National Institutes of Health. Another NRC study released shortly afterwards, *Seeking Security: Pathogens, Open Access, and Genome Databases*,[7] dealt specifically with the current practice of making genome information widely available through open databases and whether it should be changed for security reasons. The study endorsed many of the recommendations in biotechnology research, while concluding that open access should remain the fundamental practice for genome information and databases.

Although *Biotechnology Research in an Age of Terrorism* recognized the importance for policy of moving beyond biosecurity issues, it focused on these issues in the United States and also on microbial threats. To address these significant aspects of potential threats from advances in biotechnology, the National Academies next undertook a study that explicitly examined the global dimensions of a wide range of developments in the life sciences and the other disciplines with which these fields increasingly interacted. *Globalization, Biosecurity, and the Future of the Life Sciences* (also called the Lemon-Relman Report after Co-chairs, Stanley Lemon and David Relman) is frequently cited.[8] The report is especially useful for analysts who are interested in its detailed accounts of the increasing globalization

of life sciences research and in the much broader array of science and technology that is relevant to understanding the accelerating advances in the life sciences.

One of the strengths of an institution like the National Academies is its ability to build a body of work on a topic, so that over time its major themes and messages acquire additional force.[9] The reports of the National Academies on biosecurity cited offered a number of findings and conclusions related to the topics of the 2008 intersessional meeting:

- misuse of research with dual-use potential could pose a serious risk for biological weapons and bioterrorism;
- scientific community has a role and a responsibility to help reduce the risks of misuse;
- in addressing these risks a "web of prevention" is most likely to be effective;
- this web requires a mix of policies that can both enhance security and enable continuing scientific advances;
- responsible stewardship will be needed throughout the life cycle of research, from proposal to publication and dissemination;
- stewardship could include both formal approaches, such as legal and regulatory measures, and informal approaches, such as self-policing and guidelines;
- preference should be given to approaches that involve self-governance by the scientific community and guidelines by governments;
- there is an important role for "soft law"—norms, codes of ethics, conduct and practice;
- biosafety and laboratory biosecurity are essential elements of responsible stewardship and may be the best place to begin for some states;
- advice from the scientific community is important for the design and implementation of measures to promote responsible stewardship;
- there are significant roles for scientific organizations at many levels, local through international, in working with policymakers; and

- successful development and implementation of responsible stewardship will require continuing efforts to raise awareness and education for the scientific community, in which scientific organizations and professional societies can play an important role.

A number of other reports from the National Academies have reinforced some of these messages.[10]

THE ENGAGEMENT OF INTERNATIONAL SCIENTIFIC ORGANIZATIONS

Another major message from the reports by the National Academies is the importance of international efforts.[11] This reflects the recognition that science is an increasingly global enterprise with a growing diffusion of life sciences research and industry. Actions at the national level are essential and important, but to be effective any effort to address dual-use issues ultimately must be international in scope. Thus, much of the work of the National Academies on dual-use issues in recent years has been in partnership with others—in particular international scientific organizations. The National Academies' work has benefited from the ability of international scientific organizations to work directly with international bodies or convention arrangements, such as that for the BWC, in ways that national organizations generally cannot. In addition, almost all of these international organizations have national affiliates or adhering bodies, and some also have regional networks. Efforts to address dual-use issues can thus take place on multiple levels.

CODES OF CONDUCT AND THE FIRST INTERNATIONAL FORUM ON BIOSECURITY

The role of codes of conduct for scientists has been a continuing focus of interest with regard to dual-use research issues. There are several kinds of codes, each with a difference purpose.[12] As used here and elsewhere, "codes of conduct" is the preferred general term. For example, as a result of the recommendations of the Policy Working Group on the United Nations and Terrorism, the General Assembly and the Security Council passed resolutions in September 2002 calling on the Secretariat to reinforce ethical norms and prepare relevant codes of conduct for scientists involved

in technologies that could produce weapons of mass destruction. The Under-Secretary-General for Disarmament Affairs asked the International Centre for Genetic Engineering and Biotechnology (ICGEB) to assist the Secretariat in this task in relation to the life sciences.

Codes were also the topic for the 2005 BWC Intersessional Process and this led to the first engagement of several international scientific organizations with the BWC. Initially, the InterAcademy Panel on International Issues (IAP) turned out to be the primary actor among the organizations, but its partnerships with others were essential to the broader task of engaging the scientific community. In February 2004 the IAP Executive Committee adopted a biosecurity initiative and formed a small working group under the leadership of the Accademia Nazionale dei Lincei, in Italy.[13] Other members of the Biosecurity Working Group included the Academies of China, Cuba, Nigeria and the United States. In September the UK Royal Society joined the Working Group, and later that year the Royal Netherlands Academy of Arts and Sciences (Koninklijke Nederlandse Akademie van Wetenschappen) took over as chair.

Rather than attempting to develop a full-blown IAP code of conduct, the Working Group focused its efforts on drafting a statement of principles that could serve as the basis for efforts by national academies and other science bodies to develop codes of their own. This reflected a view that codes are most effective when those adhering to them have some sense of "ownership", and that this is best achieved when codes come from local or national sources with which people have closer and more direct ties.

In November 2004 the IAP Executive Committee agreed to a proposal from the NAS to serve as a co-convener for the International Forum on Biosecurity. The InterAcademy Medical Panel (IAMP) and the International Council for Science (ICSU) also agreed to serve as co-conveners at approximately the same time. The International Forum was held in March 2005 at a conference center in Como, Italy, with the stated goals of:

- Broadening the debate and advancing the awareness in the life sciences and biomedical research communities—and in the international scientific community more generally—about the challenges posed by the dual use dilemma;

- Serving as a major convening and coordinating mechanism to share information about activities already under way or being planned to address biosecurity issues;
- Providing an opportunity for a discussion of these activities, for identifying potential gaps and needs and for how they might be filled, and, in this context, exploring opportunities for future international cooperation and collaboration.[14]

Over 50 participants from 20 developed and developing countries and several international organizations took part in the Forum, which included both plenary sessions and day-long parallel sessions devoted to specific topics—codes of conduct, "sensitive" information and publication policy, and research oversight—that enabled in-depth discussions. Although the participants were mostly scientists identified through the IAP, the ICSU and the IAMP, participants also included experts from a number of other policy projects on biosecurity, as well as staff from the International Committee of the Red Cross, the Organization for Economic Co-operation and Development, and the World Health Organization. The IAP draft statement was discussed extensively during the small group session on codes of conduct and revised in response to the comments and suggestions.

The rules of the Forum precluded reaching formal conclusions or making recommendations, but the ideas generated in the working sessions were summarized and circulated informally among the convening organizations as a basis for future activities. At its meeting in April 2005 the ICSU Executive Board endorsed further work on biosecurity by the organization and its member unions, setting the stage for further engagement and collaboration.[15]

The BWC Meeting of Experts took place in Geneva in June 2005. As previously mentioned, the meeting's focus on codes of conduct provided an opportunity to encourage scientific organizations to engage in biosecurity issues. As an important new precedent, the United Kingdom, which chaired the meeting, offered a variety of professional organizations, NGOs and outside experts the opportunity to make brief presentations to the diplomats attending the meeting in a special role as "Guests of the Chair", in addition to the typical NGO statements that are part of many such meetings. The foreign secretary of the Cuban Academy of Sciences presented a draft of the IAP Statement.[16] Three of the ICSU unions as well as ICSU Deputy Executive Director also made presentations. Following

her presentation and her experience with the meeting, the president of the International Union of Biochemistry and Molecular Biology (IUBMB) convened a working group, which created a brief code of ethics for the union.[17] The International Union of Microbiological Societies (IUMS) also created a code and has urged national affiliates to adopt it and craft their own, more extensive codes relevant to local conditions.[18]

The final IAP statement was released on 1 December 2005, just in time for the Meeting of States Parties. The Chairman of the Meeting mentioned the statement in his opening remarks and officially circulated the statement to all the delegations.

THE SECOND INTERNATIONAL FORUM ON BIOSECURITY

The continuing engagement and opportunities for scientific organizations to play a role in biosecurity persuaded the IAP Biosecurity Working Group to hold a second forum that brought together organizations and individuals already active in the field of biosecurity. In 2008 the BWC Meeting of Experts, with its focus on topics directly relevant to the interests of the scientific community, once again provided an important focal point for the Forum. Reflecting the topics to be covered at the meeting, the Forum assessed the challenges and opportunities to:

- Build a culture of responsibility within the science community regarding biosecurity through education and awareness raising, codes of conduct, and other mechanisms;
- Identify standards and practices for research oversight from the review of proposals through the conduct of research, publication, and communication, and the range of approaches to achieving their widespread adoption;
- Provide scientific advice to governments and international organizations and develop the role of the science community in global governance.[19]

The Working Group turned to its partners from other activities to be co-sponsors of the Second International Forum. The IAMP agreed to help identify participants from developing countries. The leadership of the ICSU, however, urged that some of the relevant international scientific unions be approached directly, since this was the type of activity to which they

would bring particular expertise and which might also foster additional cooperation among them. Ultimately, the Forum became a partnership among the IAP, the IAMP, the IUBMB, the IUMS and the International Union of Biological Sciences, with the Hungarian Academy of Sciences hosting the Forum in Budapest and the NAS serving as the secretariat and taking responsibility for preparing a summary of the workshop. More than 80 people from 31 countries and six international organizations took part in the two-and-a-half day meeting that combined plenary sessions and working groups.

CONTINUING WORK ON EDUCATION

A recurrent theme in the activities and reports discussed in this chapter is the importance of education for reinforcing the fundamental norm embodied in the BWC against the use of disease as a weapon and mitigating the risks of misuse of advances in science. At the 2008 Meeting of Experts, the US delegation announced that it would support an international workshop about education on dual-use issues under the auspices of the IAP and other international scientific organizations. The workshop, with funding from the Department of State and the IAP, was held at the Polish Academy of Science in November 2009.[20] The NAS and the IAP shared the organizing and arrangements, and the NAS took responsibility for preparing the report, appointing an ad hoc committee, the majority of which were international members. The IAP was joined by two international scientific unions—the IUMS and the IUBMB—as partners in the project. The project's basic goals were to:

- survey strategies and resources available internationally for education on dual use issues and identify gaps;
- consider ideas for filling the gaps, including development of new educational materials and implementation of effective teaching methods; and
- discuss approaches for including education on dual use issues in the training of life scientists.[21]

More than 60 participants from almost 30 countries took part and included practising life scientists, bioethics and biosecurity practitioners, and experts in the design of educational programmes. The participants' backgrounds and experience reflected two basic themes for the workshop:

- To engage the life sciences community, the particular security issues related to research with dual use potential would best be approached in the context of responsible conduct of research, the wider array of issues that the scientific community addresses to fulfil its responsibilities to society.
- Education about dual use issues would benefit from the insights of the "science of learning", the growing body of research about how individuals learn at various stages of their lives and careers and the most effective methods for teaching them, which provides the foundation for efforts in many parts of the world to improve the teaching of science and technology at all levels of instruction.[22]

The report of the workshop contained a number of conclusions and a list of general and specific recommendations to promote greater attention to dual-use issues in the education of life scientists. In addition, several follow-up activities are being developed and implemented in support of its recommendations.

CONCLUSION

A substantial portion of the progress made over the last decade in engaging the international scientific community in dual-use issues can be attributed to the opportunities provided by the BWC Intersessional Process. The Meeting of Experts and the Meeting of States Parties provided national and international scientific organizations with important occasions around which to focus their efforts. In turn, it is hoped that their participation in the meetings made productive contributions to the growing role of the BWC as a forum for key stakeholders to address the challenges of biological disarmament and non-proliferation.

CHAPTER 20

VIEWS FROM THE FIELD II: THE IUPAC AND THE OVERSIGHT OF SCIENCE

Graham Pearson

THE IUPAC

The mission of the International Union of Pure and Applied Chemistry (IUPAC) is to advance the worldwide aspects of the chemical sciences (the term "chemical sciences" is used here to refer to chemistry, broadly defined, and to those disciplines and technologies that make significant use of chemistry) and to contribute to the application of chemistry in the service of mankind.[1] In so doing, IUPAC promotes the norms, values, standards and ethics of science and advocates the free exchange of scientific information and unimpeded access of scientists to participation in activities related to the chemical sciences. IUPAC currently has 56 National Adhering Organizations[2] (NAOs) and three Associate National Adhering Organizations (ANAOs).[3]

The IUPAC has been engaged in the oversight of science in the context of the Chemical Weapons Convention (CWC) since 2002, when IUPAC carried out a review of the advances in science and technology of relevance to the CWC prior to the First CWC Review Conference, in April 2003. The report of the review was widely appreciated by the states parties to the CWC and it played a useful part in the successful outcome of the First Review Conference.[4]

IUPAC WORKSHOPS

A further review of advances in science and technology was conducted at a workshop in Zagreb, Croatia, from 22–25 April 2007, prior to the

Second Review Conference, in 2008.[5] The report of this workshop again provided a useful input to the Conference and noted that:

> Review Conferences of the CWC are convened approximately every five years. Their objective is to review the operation of the CWC, to assess the progress made with its implementation, and to provide strategic guidance for the coming years. The drafters of the CWC understood the need to review the impact of advances in science and technology on the CWC from time to time, and to organize specifically required Review Conferences to "take into account any relevant scientific and technological developments". Such advances may relate to the scope of the prohibitions set out in the CWC, affect the way it is being implemented, and create opportunities for advancing international cooperation among States Parties in areas such as protection against chemical weapons (CW) and the peaceful application of chemistry. Dialogue between the OPCW [Organization for the Prohibition of Chemical Weapons] and the scientific community in evaluating scientific and technological progress also creates opportunities to advance awareness of the CWC and its requirements in the scientific, technological, and industrial communities.
>
> Advances in chemistry, the life sciences, and enabling technologies in recent years will undoubtedly create considerable benefits for humankind—advances which could lead to improved health, a better environment, and more sustainable development. At the same time, new scientific discovery may lead to new risks, including the potential of new chemical compounds as CW. In order to fully understand the impact of these new scientific and technological developments, IUPAC organized the Zagreb workshop and prepared this report.[6]

There were 68 participants from 29 countries[7] at the Zagreb workshop, who came from government, chemical industry, chemical research institutes and universities. Care was taken to include representatives from government departments, national authorities, and laboratories (17 participants from 11 countries) as well as members of the OPCW Scientific Advisory Board (SAB) (11 participants), as the success of any such workshop depends on achieving the right mixture of those who are aware of the convention as well as experts who are aware of the scientific and technological developments relevant to the convention. Technical input was also provided by the OPCW in the form of presentations and posters. The workshop had a total of six plenary sessions.

Overview and background

The first three speakers in this session outlined the background for the workshop, set out its objectives and provided background information on the CWC implementation process. To provide a basis for the subsequent discussions, they also elaborated on the evolution of the CWC verification regime, with particular emphasis on verification of non-production of chemical weapons in the chemical industry. The final two speakers provided an overview on trends in the chemical industry and future challenges to the CWC regime.

Synthesis

This session provided an overview on advances in drug discovery and development, on the emergence of synthetic biology and DNA synthesis, and on issues related to post-genomic developments including in such areas as bioinformatics.

Production technology

This session examined how fine-chemicals manufacturing was evolving in a number of countries in Asia, Eastern Europe and South America, using the BRIC (Brazil, the Russian Federation, India and China) states as a particular example of these current trends. It also provided an overview of the state of the art in catalysis and biocatalysis, the use and protection against toxic (industrial) gases, and the evolving application of micro-reactors in chemicals manufacturing.

Nanotechnology and aerosol drug delivery

This plenary session reviewed two areas of science and technology that are of importance for the targeted delivery of drugs but could also be relevant for the potential emergence of new delivery means for chemical weapons, as well as for the development of more effective means of protection against them.

Analysis

The session reviewed the current state of the art with regard to the analysis of environmental (chemical) as well as biomedical samples. These trends

were discussed in the context of the specific verification requirements of the CWC. The session also examined the current trends with regard to chemical weapon agent detectors for field use.

Medical countermeasures and decontamination

This session heard an overview on current trends in medical countermeasures, received background on the synthesis, use and interaction of certain new potential antidotes for the treatment of nerve-agent poisoning, and discussed the state of the art with regard to decontamination.

The report of the workshop set out the findings and recommendations in five groups:

- technical challenges to the CWC itself;
- technical challenges to the way the CWC is being implemented;
- improvements in the field of chemical protection;
- opportunities with regard to the fostering of international cooperation in the peaceful application of chemistry; and
- requirements and opportunities with regard to raising awareness of the CWC in the scientific community, and the need for incorporating these issues into chemistry education.

This report was taken into account by the SAB in submitting its report to the Second CWC Review Conference. This report paid particular attention to a joint project with IUPAC on Education and Outreach in the Context of the Convention by noting:

> The ongoing project between the OPCW and the International Union of Pure and Applied Chemistry (IUPAC) on Convention education and outreach, which was begun in 2004, aims to increase awareness of the Convention and its benefits.[8]

The Director-General welcomed this in his opening remarks to the Second Review Conference when he identified some important issues that he felt posed challenges to the OPCW and needed to be addressed.

> Indeed, we need to maintain—and this is my fourth point—our dialogue not just with industry and NGOs, but also with the scientific community. The OPCW's collaboration with the International Union of Pure and Applied Chemistry (IUPAC) helps reinforce the message of the Convention at an ethical level. Their own endeavours, such as the industry's Responsible Care programme and IUPAC's ethics project, are valuable initiatives towards ensuring the peaceful applications of chemistry.[9]

A key element of IUPAC is its Committee on Chemical Education, which advises on matters relating to chemistry education, including the public understanding of chemistry. In July 2005 the IUPAC and the OPCW organized a workshop in Oxford to address education, outreach and codes of conduct. The summary findings and observations[10] reached at that workshop in 2005 with regard to chemistry, education and outreach included:

> Steps need to be taken in chemistry education both at secondary and postsecondary levels to enhance the awareness of both the benefits that science and technology using chemicals can bring and of the potential for misuse in regard to illicit drugs, chemical and biological weapons, PIC [prior informed consent] chemicals, POPs [persistent organic pollutants], etc.

and with regard to codes of conduct included:

> Codes of conduct are needed for all those engaged in science and technology using chemicals to protect public health and the environment and to ensure that activities in science and technology using chemicals are, and are perceived to be, in compliance, with international treaties, national laws and regulations such as those relating to illicit drugs, chemical and biological weapons, banned and severely restricted chemicals, PIC chemicals, persistent organic pollutants (POPs), etc.

In each case the relevance to both chemical and biological weapons was noted. There is increasing recognition that the links between chemistry and biology are becoming ever closer and hence there is much benefit to be gained in the regimes for the prohibition of chemical and biological weapons being aware of developments in both regimes. It is against this background that the IUPAC was pleased to participate and contribute to the BWC Meeting of Experts in August 2008. At this meeting the IUPAC

noted that following the workshop in Oxford in 2005, it had had two task forces with regard to education:

- multiple use of chemicals and professional code of conduct, chaired by Natalia Tarasova in Moscow and completed in 2006;[11] and
- educational material for raising awareness of the Chemical Weapons Convention and the multiple uses of chemicals, chaired by Alastair Hay in Leeds and completed in 2007.[12]

The IUPAC project on multiple uses of chemicals reminds all those engaged in chemistry of the choices they face, that individual chemicals can have multiple uses, and that decisions about how they are used, including not making chemical weapons, are the responsibility of each individual. Education projects covering related themes are needed in other disciplines to introduce those engaged in the life sciences to biological weapons issues.

Consequently, the IUPAC at the 2008 Meeting of Experts recommended that that meeting should include education projects that remind those engaged in the life sciences of the choices they face, that the life sciences can have multiple effects, and that decisions about how they are used, including not to be used as biological weapons, is the responsibility of each individual.

With regard to codes of conduct, the IUPAC noted that it had a task force on recommendations for codes of conduct, which might be promulgated by the IUPAC and its NAOs. At the 2008 Meeting of Experts the IUPAC from its considerations of this topic recommended that the meeting include among its conclusions the following:[13]

> (i) Codes of conduct should be to ensure that activities in the life sciences cause no harm and thus form part of a comprehensive integrated approach to ensuring compliance with international treaties, national laws and regulations such as those relating to the life sciences, illicit drugs, chemical and biological weapons, banned and severely restricted chemicals, etc.
>
> (ii) Codes of conduct should emphasise the importance that activities are both in compliance and perceived to be in compliance with the Convention and national implementation legislation.

(iii) Codes of conduct should emphasise that those engaged in the life sciences will not knowingly engage in activities prohibited by the Convention or national legislation.

CONCLUSION

The experience of the IUPAC has shown that there is immense value to the CWC by the involvement of experts engaged from academia, industry and government conducting a survey of the scientific and technological developments of relevance to the convention during the year prior to the CWC Review Conference. Such involvement is of mutual benefit, as it not only ensures that those concerned with the CWC have the benefit of the best possible advice regarding such developments, but it also helps to increase awareness among the wider community engaged in chemistry of the responsibilities arising from the CWC and thereby facilitate the comprehensive implementation of the convention. The related IUPAC projects on education and outreach and recommendations for codes of conduct are valid models for the life sciences community and the international unions concerned with the life sciences with regard to the effective implementation of the BWC.

CHAPTER 21

VIEWS FROM THE FIELD III: AWARENESS-RAISING SEMINARS

Brian Rappert

States parties to the Biological Weapons Convention (BWC) have long identified the importance of making the prohibition of biological weapons known within scientific and technical communities. Most recently, the need to encourage awareness among practitioners was reaffirmed at the 2008 meetings.[1]

This chapter examines efforts over five years to raise awareness of the prohibition and the dual-use aspects of the life sciences. Dual-use here refers to the potential for knowledge and techniques generated to enable new destructive capabilities. This is treated as a distinct issue from the dual-use potential for pathogenic agents or laboratory equipment.

I, together with Malcolm Dando of the University of Bradford, among other colleagues, have been conducting interactive seminars with practising scientists and students since 2004. These have been undertaken now with over 3,000 participants in 17 countries. The purpose of the seminar was to inform about current science-security debates and generate discussion about how research should be communicated, whether it should be subject to further oversight and how it should be funded.

The purpose of this chapter is to highlight the experiences associated with these seminars and identify lessons for the future. Those lessons reveal both how to engage practitioners and how such individual engagements can provide the opportunity for states to develop education policies.

THE LIFE SCIENCES, BIOSECURITY, AND DUAL-USE RESEARCH SEMINARS

The seminars began in 2004 under a UK Economic and Social Research Council grant. Originally, they were intended as a way of getting feedback about the prospects for a code of conduct to avoid the malign application of the life sciences (the topic of the 2005 intersessional BWC meetings).

From the start we thought it important to promote debate between colleagues and students. While some science organizations have contributed to international disarmament activities for many years, our starting belief was that practising scientists would be less familiar with these issues. To avoid the seminars turning into a debate between "us" and "them", we sought to encourage dialogue between peers.

The seminars were set up as question and answer sessions built around cases. The aim was to find ways of making explicit what was implicit—meaning that we wanted to probe the assumptions and thinking underlying participants' reactions to our questions. The seminars addressed three basic questions:

- Are there experiments that should not be done?
- Are there limits on communication?
- What is the advisability of oversight measures?

After participants' initial reactions we gave subsequent information and questions that required them to elaborate their thinking and provided the basis for others to comment on what was said. One of the early lessons we learnt was the difficulty of getting groups of life scientists together. Instead of trying to do this, for the most part we made use of the existing research seminar series in universities and (less often) public research institutes. With regards to resources and logistics, this proved a highly advantageous forum.

Phase One (2004–2005)

Twenty-five seminars (two were pilots) were conducted between October 2004 and May 2005 in the United Kingdom. Our attempt to use the seminars to probe the prospects for codes was frustrated by the lack of

familiarity with dual-use debates or related security policy discussions. While some unfamiliarity was expected, the extent surprised us. As a result, the seminars were limited to a basic awareness-raising purpose.

In many ways the responses we heard to the central question posed were the ones expected. Overall scepticism was voiced about the advisability of pre-project dual-use oversight proposals.[2] Participants overwhelmingly doubted the wisdom of restricting scientific publications because they were said to provide information that would be useful for a range of peaceful and defensive efforts. In simplified terms, the recurring response to the questions we asked could be characterized as "we need to know". Hence, we as seminar facilitators sought to question where this need to know ended. Through the slide presentations, it was clear for many participants that the communication of dual-use concerns to the public or politicians was such a limit. Expressions given of where communication was no longer such a good idea provided the basis for subsequent group discussion and mutual understanding.

A Bradford BWC Briefing Paper entitled *Codes of Conduct for the Life Sciences: Some Insights from UK Academia* was produced about these seminars.[3] This interim paper was written to assist the deliberations by states parties at the BWC Meeting of Experts in June 2005. Among its conclusions was that there was little evidence that participants:

- regarded bioterrorism or bioweapons as a substantial threat;
- considered that developments in the life sciences research contributed to biothreats;
- were aware of the current debates and concerns about dual-use research; and
- were familiar with the BWC.

A central conclusion drawn was that if states parties wished to engage practising scientists in debates about codes of conduct, it first necessary to undertake significant awareness-raising activities. Further, there seemed a significant divergence between the preoccupations of participants and those within science and security policy. It was argued that within universities there was every reason to consider whether the longer-term awareness-raising strategy should involve the development of educational provisions.[4]

Phase Two (2006)

In this phase we expanded outside the United Kingdom through a grant from the Alfred P. Sloan Foundation—the funder that also supported all subsequent phases. The comparative focus was taken to see whether discussions would vary by national context as well as to develop widely appealing educational resources. In total 27 seminars were undertaken: 14 in the United States, seven in South Africa, four in the Netherlands and two in Finland.

Unlike the initial round in the United Kingdom, the planning was undertaken in partnership with government-related bodies (the Finnish Foreign Ministry), professional associations (the National Academy of Sciences and the Royal Netherlands Academy of Arts and Sciences), and members of civilian society (the Institute for Security Studies, ISS). Despite this, gaining access often proved difficult. Perhaps the most successful model for collaboration was with Chandré Gould of the ISS. As a member of the South African Council for the Non-Proliferation of Weapons of Mass Destruction and with her extensive research contacts, she was able to act as a local collaborator.

Going into this second phase, we hypothesized that responses would vary considerably across states. In practice, however, we found the questions brought remarkably similar responses and that the logic of our questioning remained appropriate. The responses differed not so much in what was said but in the social interactions of how things were said. Details of the similarities and the matters of difference were detailed in a Bradford Review Conference paper entitled *In-Depth Implementation of the BTWC: Education and Outreach*, which was presented at the Sixth Review Conference.[5]

We produced two interactive resources from this phase of the seminars.[6] However, by the end our experience also suggested that it was not enough simply to produce quality education materials. If they were to be taken up, then this would require nurturing contacts and supporting interest.

Phase Three (2007–2008)

As part of this round, seven seminars took place in India, seven in Japan, five in Israel, four in Argentina, four in Uganda, three in Australia, three

in Kenya, three in Ukraine and one in Germany. We also broadened out the types of institutions visited well beyond academia. Through this it became apparent that the interactive seminar design was appropriate for initiating engagement about dual-use issues within policy communities as well as between science and policy communities. The overall conclusions we drew from the seminars were much the same: a low prior recognition of dual-use issues by practising policymakers, scientists and students; remarkable similarity in the reasoning and responses of attendees across countries; and the insufficiency of merely devising educational materials to ensure their uptake.

On the latter point we sought to embed dual-use educational instruction into national contexts by: using the South African model of working with a local collaborator who would be trained in conducting the seminars; holding additional meetings with government and professional bodies; and building contacts in policy, scientific and medical communities. As a result, our trips became ways of prompting policy discussions in the countries visited.[7]

Phase Four (2008–2010)

In this final phase, some 22 seminars were undertaken in Australia, China, Israel, Japan, Sweden, Switzerland and Ukraine. As part of the continuation of the transformation of the research and practical agenda noted above, the seminars were only one (and generally a small) component of the way we tried to advance awareness. Such seminars were done hand and hand with other activities: train-the-trainer sessions, the creation of formal and informal national groups to further implementation; high level meetings with policymakers; national meetings; and surveys of university teaching curriculum. A goal was to build resources, networks, and policy implementation models that make it easier for others to follow. The lessons from many of the countries visited were distilled together in a 2010 volume entitled *Education and Ethics in the Life Sciences* and freely available online.[8]

CONCLUSION

Our experience suggests that fostering education about dual-use issues and the prohibition of biological weapons is possible with limited resources.

While educational materials need to be sensitive to national situations, we were surprised at the overall consistency in what we heard from participants from different countries.

Yet our experience also points to how practically implementing education in this area is a highly demanding task. To raise awareness among life scientists, much could be gained from a concerted plan for action at the international level. This could help steer, support and inspire activities within national and subnational contexts. The 2011 BWC Review Conference provides an excellent opportunity to develop such a plan. Joint actions between state parties could include mutual targets, deadlines and milestones, the establishment of international and regional coordinators, a programme of workshops, and agreed bilateral and multilateral assistance.

CHAPTER 22

VIEWS FROM THE FIELD IV: ONLINE TRAIN-THE-TRAINER MODULES IN DUAL-USE BIOETHICS AND BIOSECURITY

Cathy Bollaert, Malcolm Dando and Simon Whitby

The online train-the-trainer module in applied dual-use biosecurity education was established in recognition of the potential that exists for producing beneficial life science research that might be misused and directed for purposes such as biowarfare and bioterrorism and in recognition of the need for awareness-raising and educating the life science community regarding this problem.[1] This has given rise to what is now widely known as the "dual-use dilemma" and there is growing concern and debate about the dual-use nature of life sciences research with implications for biological weapons-making.

Historically, this dual-use potential has been underappreciated by the life sciences and wider communities and research has been conducted that confirms this to be the case. Indeed, discussions in 16 different countries with several thousand life scientists in over 110 different departments revealed a significant lack of biosecurity awareness.[2] In seeking an explanation, further surveys were carried out suggesting that only 3 out of 57 universities identified in the survey offered some form of specific biosecurity module, and in all cases these were optional for students.[3]

Nonetheless, following the September 11 attacks and later the anthrax attacks in December 2001, and following a number of experiments of concern, including the synthetic reconstruction of the polio virus based on information that was made freely available on the Internet, the need to address the security implications of scientific research through education about dual-use has gathered momentum. Subsequently, there have been international calls to promote education and awareness-raising among life scientists on the dual-use aspects of scientific research, and among peace and conflict resolution specialists.

A significant response came from the states parties to the Biological Weapons Convention (BWC) in 2008 who agreed on the value of education and awareness-raising programmes including, "covering the moral and ethical obligations incumbent on those using the biological sciences"—with the aim of building a culture of responsibility.[4] More recently, however, in a statement on the upcoming Seventh Review Conference in December 2011, the Group of Eight (G8) agreed on the importance of promoting "work on better awareness raising among those involved in the development of life sciences in order to limit the possibilities of misuse of technical developments, including supporting dual-use education programmes on bioethics".[5]

IMPLEMENTING DUAL-USE EDUCATION ON BIOETHICS AND BIOSECURITY

There are a number of easily achievable and affordable methods of building a worldwide sustainable capacity and competency in dual-use bioethics and biosecurity education among life scientists. One of the most efficient and effective ways of doing this is through the development of online train-the-trainer modules. To this end, the University of Bradford is currently delivering both a 20 credit masters-level module and a six-week certificated course in applied dual-use biosecurity education.

The courses are delivered online using interactive virtual learning e-platforms, where course participants can explore real-time, face-to-face lectures on issues of relevance to dual-use biosecurity and address concerns and dilemmas that result from activities in the life sciences.

The courses were first implemented in September 2010 and have so far attracted a range of distinguished professionals—including members of the State Party Delegations to the BWC and highly-accomplished life science professionals from countries such as Egypt, Indonesia, Jordan, Kenya, Morocco, Nigeria, Pakistan, the Philippines, Qatar, the Russian Federation, Uganda, the United Arab Emirates and Yemen. Part of the attraction of the course is that it is delivered entirely online using a range of information and communications technology (ICT). Not only does this significantly reduce the cost by avoiding unnecessary travel expenses, it also renders it flexible and easily accessible to those with heavy work schedules. To illustrate its versatility, in the space of 12 weeks (the duration of the module) one

participant, a professor in biotechnology, accessed and participated in the course from seven different countries.

With the objective of building capacity and competency in dual-use bioethics and biosecurity, one of the key outcomes of the course is for participants to be able to contribute to the practical development of biosecurity. This is measured against the learning outcomes set by the course module descriptor which include the following:

- knowledge and understanding—participants will be able to review and appraise ethical and biosecurity theories and methods relevant to dual-use;
- discipline skills—participants will be able to organize and synthesize ideas and questions relevant to assessing ethical dilemmas in specific dual-use issues affecting humans, animals and plants, as well as integrate dual-use biosecurity issues and concerns into the training of others; and
- personal transferable skills—participants will be able to communicate and collaborate effectively in an online environment with their colleagues and students using a range of media and ICT tools.

In seeking to achieve these learning outcomes and with the aid of online technologies, the course allows participants to engage in discussions built around the key themes of the course. Thus, the lectures have been designed to address the themes identified as being of central importance to the development of an informed appreciation of dual-use biosecurity so as to cover a range of issues of relevance including an understanding of the:

- threat of offensive biological warfare programmes and bioterrorism;
- international prohibition regimes, including the Geneva Protocol,[6] the BWC, the Chemical Weapons Convention and Security Council resolution 1540;
- dual-use dilemma;
- responsibilities of life scientists and responsible conduct of research;
- importance of national implementation of the BWC; and

- wider web of preventative policies that together minimize the risk of the hostile misuse.

During the course participants are encouraged to work together in online groups with colleagues from different countries to show how they might address the bioethical dilemmas in the given real-life scenario. In doing so, participants engage in a case study approach applied in seminar scenarios which are based on real-life, expert-level scenarios—including the case of Thomas Butler, mousepox, Spanish flu and the synthetic polio virus. These scenarios allow life scientists to develop an informed appreciation of the range of dual-use dilemmas. Moreover, participants are encouraged to bring their own personal ideas and experiences to the course in order to contextualize knowledge and understanding in ways that will help meet the ethical challenges thrown up by dual-use concerns.

Forming part of the assessment, participants are asked to show how they might utilize the information on dual-use bioethics and biosecurity in an education module resource (EMR)[7], which is freely available online, through its assimilation in the teaching of others in their own professional context. In addition to the delivery of an online group work presentations, participants are required to write a 2,000 word report on how they would address the dual-use dilemma they have been presented with. Lastly, a 4,000 word, individual essay forms the final component of the academic assessment. Participants are also presented with an action plan. This is aimed at stimulating reflection and developing awareness of dual-use concerns in the participants' respective institutions and associations. On successful completion of the module, participants are awarded with 20 UK masters-level credits and certification of continuing education.

ACHIEVABLE AND EFFECTIVE OUTCOMES

Whilst the lectures and seminars are delivered using *Elluminate*—a virtual classroom enabling the interaction of participants in real-time—participants also engage with the course material using Ning—a social networking site which has become a significant ICT tool for facilitating the building of sustainable capability in dual-use bioethics and biosecurity. First, it provides a variety of tools for enhanced learning—for example, allowing members to post discussions and videos on relevant topics. Secondly, it provides a platform to establish a network of biosecurity competent members. This

is further strengthened through collaboration fostered by the online group work presentations. As this is an expanding network of practitioners from numerous countries, it provides a novel means for the dissemination of research on the subject. In doing so, it is contributing to achieving much-needed cultural exchange in life science education and practice.

An empirical analysis of the online train-the-trainer module in applied dual-use biosecurity education shows how effective the course has been. Despite its recent launch, in September 2010, the programme, over and above the training of over 30 life scientists, has achieved the following outcomes:

- alumni who previously had no knowledge or appreciation of dual-use concerns are already integrating the training into their own teaching;
- alumni have organized and facilitated workshops among their professional associations and within their national public health structures;
- the participation of a trainer who was directly responsible for writing the national guidelines for the development of a code of conduct for life scientists in Pakistan;[8] and
- the participation of the Chairman of the National Biological Weapons and Toxins Committee in Kenya, who is in the process of developing an educational hub in Kenya through which dual-use biosecurity education can be disseminated in East Africa.

CONCLUSION

As trainers participate in a process of active, flexible online learning about the importance of dual-use bioethics and biosecurity awareness-raising, and as networks of ethically-aware life scientists expand, initiatives such as this will surely serve to further enhance and reinforce a culture of responsible conduct of research in the life sciences. Indeed, the Presidential Commission for the Study of Bioethical Issues recently pointed out that educational initiatives could represent the single most important development in strengthening responsible conduct of research in the life sciences.[9] From informal discussions with our network of dual-use bioethics and biosecurity trainers, there is at least anecdotal evidence that demand for such train-the-trainer programmes is increasing.

SECTION D

DEALING WITH DISEASE REGARDLESS OF CAUSE

CHAPTER 23

ADDRESSING THE SPECTRUM OF BIORISKS

Marius Grinius[1]

The aim of the Biological Weapons Convention (BWC) is to prevent biological weapons ever being used and to ensure that biology is used solely for peaceful purposes. It does this in a variety of ways, including through legal frameworks (such as the legal prohibitions on developing, producing, acquiring, transferring, stockpiling and using biological weapons); institutional arrangements (such as oversight frameworks to ensure biology is not diverted from its intended use); and practical, physical efforts (such as the commitment to strengthen national disease surveillance, prevention, mitigation and response measures to minimize the likely impact of the use of these weapons—reducing the threat they pose and decreasing their utility).

The BWC, under Article X, also contains a commitment to facilitate the peaceful use of biology. Through the BWC, all states parties have agreed that they must work together on strengthening health security. Whilst preventing the acquisition and use of biological weapons, states parties need to make sure their security activities, whenever possible, provide spin off benefits for health. In the pursuit of its objectives, the BWC must also avoid duplicating existing international efforts in the health arena and take advantage of existing health resources. This necessitates strong working ties between those whose primary focus is on addressing natural disease and those of us who spend our time dealing with the possibility of deliberately instigated disease. Both of our efforts are designed to address an interconnected set of causes for disease.

BIORISKS AND THREATS

There is a spectrum of different causes for disease events (see Figure 23.1). They range from those with completely natural origins, through

unintended consequences, accidents, and those caused by negligence, to acts of vandalism or sabotage, all the way to deliberately hostile acts—such as the use of biological weapons.

Figure 23.1 The spectrum of biorisks

Traditionally, the health community addresses one end of this spectrum and the BWC deals with the other. There is an increasing realization that they are both working on the same problem but from different ends. We need to find better ways to work together. The ideal solution would be to find a way for health resources to provide security benefits and for security resources to reinforce health efforts. This is what we are now trying to do.

THE SECOND INTERSESSIONAL PROCESS

The current set of BWC meetings was established by its last Review Conference, in 2006, and runs until the next Review Conference, in 2011. They discuss, promote common understanding and effective action on measures to strengthen the implementation of the convention. The BWC holds two meetings each year—the Meeting of Experts in the middle of year and the Meeting of States Parties at the end of the year. The Meeting of Experts is used to gather as much information as possible on the topics addressed in a given year. This information is processed and fed into the Meeting of States Parties, which reviews what is being done and whether it is possible to agree on doing anything more. Through this process the BWC has attempted to strengthen how it works with other regimes and to ensure that its efforts are complementary to those of its partners in dealing with biorisks and threats. The focus of recent BWC efforts, as this book illustrates, has been on national action. It has engaged in an international process designed to foster national action. The topics covered throughout this process, when taken together, make a valuable contribution to managing the spectrum of biorisks.

MANAGING BIORISK

Managing biorisks means reducing the likelihood of an event happening and mitigating its potential impact to acceptable levels. This is something that neither governments nor professional communities can do alone and necessitates finding new ways for them to work together. Irrespective of whether we are dealing with natural, accidental or deliberate disease, we need legislative and regulatory frameworks through which to work, guidance and best practices to ensure we maximize our impact, and measures to build capacity to ensure that we all share protections against disease. The BWC has contributed to each of these areas through the Second Intersessional Process.

In 2007 the BWC meetings addressed legal and regulatory frameworks for dealing with deliberate disease. They led to common understandings on elements for national legislative, regulatory and administrative frameworks, including:

- components—such as the requirement for effective import and export controls;
- mechanisms—such as defining roles for all the relevant agencies and departments;
- enforcement capacity—such as the need for training for law enforcement; and
- ongoing activities—such as regular review of measures.

It also led to common understandings on regional and subregional cooperation on implementation, including:

- approaches—such as making best use of existing forums;
- provision of resources—such as making use of the Implementation Support Unit as a clearing house for assistance; and
- the importance of sharing information—such as the importance of nominating contact points.

Although not directly mandated to work on parallel frameworks in the health sector, through its 2008 meetings, which covered biosafety, the BWC reviewed arrangements in place to deal with accidental disease,

and through efforts in 2009 dealt with arrangements for natural disease, especially under the revised International Health Regulations.

With regards to best practice, the 2008 meetings developed common understandings across a large part of the spectrum. BWC efforts illustrated best practice and guidance on elements of biosafety and biosecurity, including:

- components—such as the importance of developing national and international networks of experts;
- tools—such as national lists of relevant agents, equipment and other resources;
- characteristics—such as the importance of adapting measures to local needs; and
- assistance—such as the necessity of holding courses and providing training.

The 2009 and 2010 meetings dealt specifically with building capacity, improving coordination and the provision of assistance. As a result, they made valuable contributions for dealing with disease—irrespective of its cause.

BUILDING CAPACITY TO MANAGE BIORISKS

The 2009 meetings of the BWC led to common understanding on pillars for building capacity to deal with disease, including:

- infrastructure components—such as the need for disease surveillance systems which continuously collect and analyse data from multiple sources;
- measures for developing human resources—such as ensuring the existence of training materials in native languages; and
- tools for implementing shared practices—such as strengthening international protocols for the rapid sharing of information.

In 2009 the BWC also reached common understandings on cross-cutting themes for building capacity, including:

- sustainability—such as by addressing the needs for day-to-day maintenance;
- improving integration—such as by making use of interdisciplinary, all-hazards approaches;
- enhancing coordination—such as by forging north-south, south-south and north-north partnerships; and
- overcoming challenges—such as by mobilizing resources, including financial resources, to facilitate the widest possible exchange of equipment, material and scientific and technological information.

These efforts have helped to strengthen the convention by enhancing international cooperation and exchange for peaceful purposes, and improving capabilities for preventing and responding to illicit uses of biological agents and toxins. These meetings provided an important opportunity for those needing assistance to say what they need and for those in a position to provide it to outline what capacity-building they might be able to provide. It led to new partnerships being formed and through them a tangible increase in capacity to deal with disease.

The work of the BWC in 2009 exemplified efforts to improve how states parties to the convention work domestically, among each other and with third parties. Efforts included:

- surveying the landscape of topic—through background information papers and national presentations;
- identifying and interacting with the international, regional and professional organizations already dealing with these issues;
- sharing information on national activities—through working papers, statements, presentations and contributions to compendiums of national approaches; and
- enabling the effective and efficient exchange of offers of and requests for specific assistance and cooperation to build capacity in the area and complement the activities of others.

Much of the benefit of the recent work of the BWC happens outside its meetings. Simply counting the number of participants or formal agreements reached does not indicate its full value in building capacity.

It is much harder to assess the value of the networking opportunities offered, the partnerships founded through connections made over coffee, or the impact of shared experience upon returning to the capital. The only metric we have is the feedback received from states—and this has been overwhelmingly positive.

A COMMUNAL CHALLENGE

Ensuring that biology is used safely, securely and solely for our benefit is a burden we must shoulder collectively. It is not something that can be left to a few states or pursued by governments alone—or even pushed on to the shoulders of communities whose priorities lie elsewhere. Dealing with a subset of disease is what the BWC was created to do. If we are to engage in this issue in a meaningful way, then we cannot do it in isolation. We must acknowledge and work with the regimes created to address other parts of the spectrum. The good news is that this means we have powerful partners out there to help us. Some of them are addressed in the next few chapters which will cover: the World Health Organization's efforts to build global capacity for health security and its arrangements for alert and response; efforts by the World Organisation for Animal Health to foster good governance; and the current status of international disease surveillance for plant diseases.

Given that we know that disease knows no borders and the speed at which infectious disease can spread around the world through our transportation networks, it is increasingly important that every country in the world is covered by core prevention, mitigation and response capabilities. We know that there will be no single solution to what these core capabilities will look like or entail. They will need to be tailored to the specific needs and capacity of each state.

CHAPTER 24

PROVIDING ASSISTANCE AND COORDINATING RESPONSE FOLLOWING THE USE OF A BIOLOGICAL WEAPON

Pedro Oyarce

In 2010 the Biological Weapons Convention (BWC) looked at the provision of assistance and coordination with relevant organizations upon request by any state party in the case of alleged use of biological or toxin weapons, including improving national capabilities for disease surveillance, detection and diagnosis, and public-health systems. This is an important topic that goes to the heart of key obligations in Article VII of the BWC to provide assistance to states parties which are exposed to danger as a result of violations of the convention. To focus our efforts, I encouraged states parties to consider the practical question: if a biological weapon were to be used tomorrow, how would we, the states parties, individually and collectively respond?

From the outset it was clear our deliberation would have a number of different dimensions (see Figure 24.1). Relevant efforts can be broken down into national and international categories. There are national measures for assistance and response to alleged use, such as the mechanisms developed by the governments of individual states parties or national needs for assistance and capacity to offer such assistance. There are also international measures for assistance and response to alleged use, as developed collectively by members of a convention or by international organizations, including relevant capacity-building activities. Our topic could also be broken down according to the type of assistance and response. Some efforts are important to respond to the effects of alleged use, such as a public-health, veterinary and humanitarian response, an emergency response, efforts to control the spread of disease, and measures for caring for victims or decontamination, among others. This might be called the "health" dimension for short. There are also efforts to find the cause of

an alleged use, such as the technical or criminal investigation to identify the source of the outbreak or incident. This could be called the "security" dimension. It was important that throughout our work we consider all these aspects, drawing on the experience and expertise of national and international experts from a range of disciplines and agencies.

Figure 24.1 A conceptual framework for responding to alleged use

	National	International
Health	National capacity for public health/veterinary and humanitarian response	International public health/ veterinary and humanitarian response channels
Security	National forensic investigation capacity	International mechanisms and assistance for investigation

Approaching this topic in this manner highlighted some important considerations:

- Who are the relevant actors at the national, regional and international levels?
- What are the operational considerations?
- What is already being done in the field of emergency assistance, both nationally and internationally?
- Which areas require further development and coordination?

THE WORK OF THE BWC IN 2010

We produced a vast array of valuable, compelling material on every aspect of responding to alleged use of biological and toxin weapons. We heard authoritative and deeply informative perspectives from developed and developing countries, from international and regional organizations, and from health, agricultural and security experts. In my opinion it would be essential to continue providing assistance for a broad participation

of experts from different regions, particularly from the developing and least developed countries. This inclusiveness is a key element to the promotion and implementation of the convention and important for its universalization.

From what I observed of the work of the BWC in 2010, states parties are very well aware of the threat biological weapons pose to international security. There was clear recognition that our work laid the foundations for future elaboration on this important issue. I am convinced that our discussions in 2010 were an important step in highlighting the challenges that the international community faces in responding effectively to the alleged use of biological weapons, and in finding ways to overcome these challenges.

The common understandings we reached highlighted the importance of pursuing relevant initiatives through effective cooperation and sustainable partnerships.[1] The common understandings also highlighted the relationship between national preparedness and international capabilities. States parties also identified a number of practical ways to work together to build specific national capacities. In addition, they highlighted the importance of sharing best practices, of improving communication and information management and of strengthening the coordination between relevant national and international organizations, within their mandates, for an effective preparedness and response. I was keen we reach an action-oriented product, and I am pleased with what we accomplished.

REFLECTIONS ON RESPONDING TO ALLEGED USE

The effective provision and coordination of assistance following an alleged use of a biological weapon is particularly important and interesting to those who seek to bridge the gaps between regional groups. It unites the "regulatory" and "promotional" aspects of the convention. Improving national capabilities to respond to alleged use of biological weapons directly supports the security objectives of the convention. It also directly supports the implementation of Article X of the convention, promoting the development of the peaceful applications of biological science and technology. It therefore provides a very fruitful area for developed and developing countries to work together. Combining security and

development objectives in this way is the key to making further progress in multilateral disarmament.

It was important to me that our efforts in 2010 were tailored towards taking genuinely effective and coordinated action to provide assistance and to build national capabilities for responding to disease outbreaks. To this end, I was pleased with our progress in filling in some of the blanks with which we started the year.

Who are the relevant actors at the national, regional and international levels?

Through the information submitted to our meetings and the activities of all the participants, we succeeded in identifying many of the most relevant players and engaging them in our work, including:

- Food and Agriculture Organization of the United Nations (FAO);
- International Committee of the Red Cross (ICRC);
- International Criminal Police Organization (INTERPOL);
- Organisation for Economic Co-operation and Development (OECD);
- Organization for the Prohibition of Chemical Weapons (OPCW);
- United Nations Office for Disarmament Affairs (UNODA);
- United Nations Interregional Crime and Justice Research Institute (UNICRI);
- World Health Organization (WHO); and
- World Organisation for Animal Health (OIE).

Other international organizations were deemed relevant but were unable to participate in our discussions. We also benefited from the experiences of several independent experts, including from the Philippines and the United States. As always, we were able to draw upon the efforts of a broad range of non-governmental expertise present at our meeting.

What are the operational considerations?

The output of our efforts, including the common understandings we reached, described in some detail the roles, responsibilities and needs of the convention itself, of states parties, international organizations and other relevant actors. The convention was identified as the suitable forum for bilateral, regional or multilateral consultations for the provision of prompt and timely assistance following an allegation of the use of a biological weapon. States parties recognized the value of clearer and more detailed procedures for submitting requests for assistance and for promptly providing assistance. They also felt that it was important to develop a comprehensive range of information on sources of assistance and a mechanism to request assistance. States parties recognized that they bear the primary responsibility for providing assistance and coordinating with relevant organizations in the case of alleged use of biological or toxin weapons. The common understandings they identified included components of particular importance in both health and security responses. It is necessary to foster partnerships among different actors for better implementation of the convention. States parties recognized that international organizations, in close cooperation and coordination with the states parties play an important role in the provision and coordination of assistance. Such actors were encouraged to work together more closely, to address specific relevant aspects of the threats posed by the use of biological and toxin weapons, and to assist states parties to build their national capacities.

What is already being done in the field of emergency assistance, both nationally and internationally?

Our background materials, the statements and presentations made, as well as the resulting Compendium of National Approaches all help to paint a comprehensive picture of what capacity exists, where and with whom. For example, the WHO briefed the Meeting of Experts on their likely response to allegations of a use of a biological weapon. They stressed that their primary role will be "to manage the public health consequences and communicate real-time public health risk assessments and recommendations".[2] Their briefing covered international health security, changes in epidemic control, changes in the relevant legal frameworks, effective global alert and response, as well as their work with international partners.

The same meeting was also briefed by INTERPOL on their efforts to improve communication and data sharing among police forces, as well as efforts to support operational capacity and provide training and development.[3] The meeting was informed about the efforts of the Bioterrorism Prevention Project, including:

- workshops;
- train-the-trainer sessions;
- table-top exercises;
- the development of an incident pre-planning and response guide;
- rotational fellowship programme; and
- databases, training modules and online resource centre.

States parties also heard examples of national efforts. For example, a joint presentation from the US Federal Bureau of Investigation (FBI) and the United States Centers for Disease Control and Prevention (CDC) provided practical insights into efforts to encourage health and security sectors to work together more closely.[4] Another presentation, by Kenya, outlined the regulatory frameworks and operational responses that comprise its Integrated Disease Surveillance and Response Strategy.[5] The presentation also highlighted the need in Kenya to strengthen capacity for an effective health and security response and to improve prevention.

Which areas require further development and coordination?

The common understandings reached at the Meeting of States Parties include a specific list of outstanding challenges that can be used as a roadmap for future work under the BWC:

- the need for clear procedures for submitting requests for assistance or for responding to a case of alleged use of biological or toxin weapons;
- the need for additional resources in the human and animal health fields, and most acutely in the area of plant health, particularly in developing countries;
- the potentially complex and sensitive interface between an international public-health response and international security issues; and

- the public-health and humanitarian imperatives of a prompt and timely response.

THE NEXT STEPS

If the work of the BWC in 2010 provided answers, it also generated new questions. Which steps might the Review Conference take to deal with the prospect of a biological or toxin weapon being used? Are new mechanisms required? What might these be? States parties should think boldly and must be prepared to consider and discuss new ideas, without any preconceptions. This is an issue that must be given serious consideration at the next Review Conference—not only as part of the examination of the results of the Intersessional Process, but also through the article-by-article review of the convention. We must overcome the divisions of the past and work together as we move into the future. It is of vital importance that we do know how states parties would respond—individually and collectively—to an alleged use of a biological weapon. In short, what are the concrete conditions we have to deal with in view of achieving full compliance with the convention? This is crucial for both prevention purposes and the response to alleged use. It is a matter of technical, but foremost of political definitions.

CHAPTER 25

REDUCING BIOLOGICAL RISKS BY BUILDING CAPACITY IN HEALTH SECURITY

Ali Mohammadi

Communicable diseases remain a major public-health burden in countries, causing not only illness but also incapacitation and death in humans and animals. Responding to and effectively managing outbreaks to limit their impact on populations at risk require tremendous resources that most states cannot afford, yet are expected to deliver. Therefore, many developing and transitional countries lack efficient capability to respond properly and effectively to outbreaks of disease.

Moreover, poor hygienic and safety conditions in hospitals and laboratories, as well as lack of knowledge of safe handling and transport of infectious materials, have become a major source of dissemination of infectious materials among personnel and the environment—consequently endangering lives.

On the other hand, there is increasing concern about the possible misuse of dual-use pathogens and toxins as a means of causing harm or death. This alone needs special attention and effective planning to reduce such threats, which, if not managed properly, may result in disasters to communities.

Dangerous pathogens may cause risk to public-health security through:

- natural outbreaks of infectious diseases;
- poor laboratory and clinical conditions and practices;
- careless handling of infectious materials containing dangerous pathogens; and
- deliberate misuse of such materials to cause harm, disease, incapacity or death.

OUTBREAK OF INFECTIOUS DISEASES

Infectious diseases are still the most common killers of children and young adults in marginalized and developing countries in Latin America, South-East Asia and sub-Saharan Africa. They are estimated to account for up to 45% of deaths in developing countries. In one hour alone 1,500 people die from an infectious disease—over half of whom are children under five. Of the rest, most are working-age adults—many of them breadwinners and parents. Both are vital age groups states can ill afford to lose.

Most deaths from infectious diseases occur in developing countries—the countries with the least money to spend on health care. In developing countries almost one in three children is malnourished. One in five has not been fully immunized by their first birthday. And over one third of the world's population does not have access to essential drugs. Against this backdrop of poverty and neglect, it is little wonder that deadly infectious diseases have been able to gain ground. Today some of the poorest countries are paying a heavy price for the world's complacency and neglect.

Annually there are over 500 million cases of malaria, with over 1 million deaths per year, mainly young children in sub-Saharan Africa under the age of five. Over 90% of the global disease burden, and almost all mortality, is in the sub-Saharan region.

Viral haemorrhagic fevers are the clearest examples that pose an even greater threat to public health in these countries due to:

- high pathogenicity of causative agents, which in poor sanitary conditions and health services cause severe illness, incapacitation and death; and
- transmission through different vectors predominantly living in the environment which facilitate the spread of such diseases.

These diseases are also the initial source of biological risks which can be used as effective tools for bioterrorism and add additional stress on health-care delivery, cause major economic impact and even lead to political instability in countries that are poorly prepared to face these health threats.

LABORATORY BIOSAFETY AND BIOSECURITY

Contributing risks to the spread of natural outbreak of diseases in these countries are the poor hygienic and safety conditions found in hospitals and laboratories and the lack of knowledge of safe handling of the infectious materials. Staff, patients, family members and the environment are inadvertently exposed—needlessly endangering the lives of others. The lack of basic knowledge of the fundamental elements of safety could lead to the hospital or laboratory facility becoming the source of an outbreak rather than the place for a cure, leading to the public's mistrust of the health-care system and eroding public confidence in health authorities.

Part of the creation and supporting a "safe workplace" programme also requires that health-care workers become aware of how pathogens and toxins are misused as a means of causing harm or death. Awareness allows management to support a programme which ensures that neither health-care facilities nor laboratories serve as a source of these materials. Issues surrounding dual-use potential of valuable biological materials (VBMs) need to be discussed in order to build a system to mitigate the risks of misuse. This itself needs special attention and effective planning to reduce such threats.

Therefore, the first priority in biological laboratories working with biological agents and toxins is the establishment of biosafety principles and culture within the laboratory environment through a national biorisk management programme.

A complete system of laboratory biosafety involves many different aspects, including proper laboratory procedures, sound guidelines for the transfer of pathogenic micro-organisms between facilities, regulations governing the correct use of certain equipment, and standards for building laboratories where personnel work with highly infectious or pathogenic diseases. In other words, there is a need for a new and comprehensive biosafety programme which includes regulations and guidelines applicable to all microbiological and biomedical laboratories, national standards for biosafety practices, training programmes, biological risk assessment, monitoring, and evaluation and networking of laboratories and experts. The objectives of such a programme should be:

- highlighting the importance of implementation of biosafety and biosecurity standards to protect personnel and the environment through good practices as well as safeguarding VBMs;
- emphasizing the need for institutions and laboratories, in particular in developing countries, to implement effective biosafety and biosecurity principles and practices;
- providing proper information on the principles, objectives and practices of laboratory biosafety and biosecurity guidelines published by the Food and Agriculture Organization of the United Nations, the World Health Organization (WHO), the World Organisation for Animal Health, and other international and national organizations;
- providing guidance to encourage national authorities to translate such guidelines into national regulations, norms and standards;
- implementing biological risk assessments in facilities working with biological agents and toxins; and
- providing assistance to health authorities in establishing training for laboratory management and workers on biosafety and biosecurity issues.

PREPAREDNESS FOR DELIBERATE OUTBREAKS

The use of biological agents and toxins as weapons has always been an attractive issue in terrorism. Although the development and production of such weapons have been prohibited by the Biological Weapons Convention, the world has in many occasions witnessed their development, stockpiling, transfer and use. Therefore, the deliberate release of biological agents and toxins should be considered as a major public-health risk. Standard risk-analysis principles should be used in order to determine the relative priority of such releases in comparison with other dangers to public health in the country concerned. Considerations for deliberate release should be incorporated into existing public-health infrastructures, rather than developing separate infrastructures.

Preparedness for the deliberate release of biological agents can be increased in most countries by strengthening national capacities in public-health infrastructure—particularly surveillance and response. Public

awareness and training of experts in the field and laboratories is considered to be a key element in preparedness and response to such risks.

Biotechnology and the life sciences also present potentially enormous advancements and benefits for global priorities, such as the environment, food and health. Many of these advancements may also present formidable challenges if intentionally or accidentally misused. These challenges must be confronted and successfully addressed within a biorisk management programme.

INTERNATIONAL HEALTH REGULATIONS

The International Health Regulations (IHR) provides a global framework to address these needs through a collective approach to the prevention, preparedness and response to any public-health emergency of international concern whatever the origin or source. The scope of the IHR, detailed in Article 2, is "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade".[1] The IHR require states to strengthen capacities to detect, assess, confirm, report, control and respond to events of international public health concern.

Article 5 requires that:

> Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

CAPACITY-BUILDING THROUGH A NATIONAL BIORISK MANAGEMENT PROGRAMME

Strong national health prevention and preparedness capacities and effective regional and global coordination mechanisms are essential to effectively respond to public-health emergencies involving biological risks from natural, accidental and deliberate outbreaks of disease.

To achieve such goals, a national biorisk management programme needs to be established in developing and transitional countries to build or strengthen national capacity and prepare them to respond adequately to threats. The main objectives of such a programme should include:

- raising awareness within the countries on how to prepare and respond to threats posed by outbreaks of infectious disease caused by dangerous pathogens;
- providing continuing training courses for public-health and health-care workers on biorisk management, prevention of misuse of science and best practice principles to prevent accidental or deliberate release of dangerous pathogens in the environment;
- establishing a multi-stakeholder national committee to review, implement and monitor the programme;
- employing all national capacities (experts, institutions, laboratories, public and private sectors) to respond and contain the events in a harmonized and coordinated manner; and
- establishing technical and special network of laboratories and experts working in biorisk reduction practices and management as a global resource.

OPERATIONAL PLAN

The operational plan is to:

- establish awareness and preparedness meetings, workshops and training courses at the regional and national level;[2]
- establish a strategic awareness and preparedness training curriculum and related training materials;
- develop national guidelines, procedures and checklist for national authorities to establish a system to monitor, assess and certify biosafety and biosecurity principles and practices;
- set up a train-the-trainers programme to train competent experts and establish a national and regional network of trainers;
- support exercises to maintain preparedness to respond to pandemic and epidemic outbreaks—natural, accidental or deliberate;

- support laboratory networks of highly dangerous pathogens; and
- establish an evaluation and monitoring system for laboratory biosafety and biosecurity.

Workshops

Such workshops are mainly designed for public-health policymakers and regulatory authorities to better understand the importance and concept of biorisks and create awareness and preparedness about the threats of such risks to their state's public health. The awareness workshops can be organized for laboratory directors and health workers followed by training courses. These workshops should be first organized at the regional or subregional level and given priority to states in Africa, Central Asia and the Middle East.

Training curriculum and materials

Based on the awareness workshops for policymakers, there is a need to establish a series of strategic training courses for health workers, laboratory managers and experts to create a culture of biorisk reduction and implement biosafety and biosecurity standards and practices. Therefore, a training curriculum on biorisk reduction needs to be developed. Such a curriculum should cover all aspects of biorisk reduction, including outbreak response, biosafety and biosecurity, risk assessment, laboratory networking, and life science and dual-use research.

Train-the-trainers

The idea is to facilitate training of biosafety and biosecurity in developing countries by selecting competent biosafety experts from each country and training them as trainers. Selection of these experts should be based on certain criteria to find the most qualified. Once trained, the trainers are expected to establish a national biosafety and biosecurity training programme in their country. WHO manuals[3] and other existing training materials may be used as source documents according to the level of laboratory practices and their needs.

Training courses

Once the training curriculum is developed and the training materials are produced, states can then establish training courses for their experts. The first step is to select trainees among laboratory managers and experts, which should be done in collaboration with each state's health authority. Such a curriculum may also be integrated into the educational programmes for university students in the field of life sciences.

Development of pre-qualification guidelines

In addition to a lack of knowledge of biorisk reduction, low levels of biosafety in laboratories dealing with research, diagnosis of infectious diseases and production of biological products is another shortcoming in biorisk management in developing countries. Many laboratories in countries involved in an outbreak of disease lack the basic condition to contain dangerous pathogens—even while working with them. There are also no risk assessment and certification procedures for these laboratories at the national level.

Therefore, development of a pre-qualification guideline on biorisk management and related check list will help national authorities establish a system to monitor, assess and certify biosafety and biosecurity principles and practices in biomedical laboratories.

Support preparedness and response to disease outbreaks

The programme should also provide support to outbreak response activities through its awareness and training programmes on the regional and national level. This will facilitate operation of preparedness and response activities such as field testing for preparedness for deliberate epidemics in different countries.

Support laboratory networks

Mapping, defining and establishing laboratory networks will provide a platform for improving laboratory capacity, training and collaboration. Through this network, participants will be able to exchange their capacities, synergize their efforts and have access to worldwide programmes designed to improve laboratory practices and communication.

CHAPTER 26

INTERNATIONAL EFFORTS TO REDUCE THREATS FROM ANIMAL PATHOGENS

Keith Hamilton and Kazuaki Miyagishima

Animal diseases not only impact on animal and public health, but also have significant economic consequences and threaten food security. Dynamic demographic and environmental factors ensure that infectious disease risks are ever changing. Globalization, climate change, closer interactions between domestic animals, wild animals and humans, combined with an increasing demand for food, means that the world today is especially vulnerable to the threats posed by animal diseases.

The potential impact of animal disease, the ready availability and low cost, and the relative ease with which they can be transported across borders and released in the proximity of susceptible animals all make animal pathogens ideal weapons for bioterrorists.

States with strong, well-governed veterinary services are in a better position to detect and respond to animal disease outbreaks at an early stage. This applies equally to natural disease outbreaks as well as those resulting from deliberate or accidental releases of pathogens. Strong well-governed veterinary services are more likely to prevent the misuse or accidental release of animal pathogens through effective biosafety and biosecurity measures, and ensure that biological science is used for peaceful means by overseeing animal health-related research and development activities.

IMPACT OF ANIMAL DISEASE

Livestock plays an important role in ensuring food security—livestock farming is responsible for providing around 25% of the protein needed to feed the world. Industrial production contributes a significant portion

of this, but smaller producers also play an important role, particularly in developing and transition countries. In many countries draught animals are important for farming and transporting arable and cereal crops. Livestock are considered as a pillar of livelihood in many local economies, especially among poor populations.

The economic burden of large-scale animal disease outbreaks, including direct losses to production, the costs of controlling the disease, disruption to markets, local economies and trade, can run into billions of dollars. For example, some estimates put the total cost of the foot-and-mouth disease (FMD) outbreaks in the United Kingdom at 43 billion US dollars. Large widespread outbreaks of animal disease reduce the availability of affordable dietary protein, particularly for poorer people who are first affected when food prices rise.

Farming offers a way out of poverty for many of the world's poorest. In the face of animal disease outbreaks, the livelihoods of many farmers and businesses along the food supply chain are threatened by losses in productivity and restricted access to international markets when importing countries establish trade barriers to protect themselves. With around 700 million of the world's poorest dependent upon agriculture as a source of income, farmers in developing countries are particularly exposed to the impacts of animal diseases.

It is not only agriculture and the food supply chain that suffer the effects of animal diseases. The 2001 FMD outbreaks in the United Kingdom had a serious impact on already ailing non-farming rural businesses and national tourism. Restriction on access to many parts of the UK countryside and the images of burning cattle carcasses that were broadcast around the world did little to encourage tourists to visit in the summer of 2001, leading to estimated losses of between 3.8 and 4.6 billion US dollars to the UK tourist industry. Other animal diseases may have little impact on animal health or animal production but significant impact on related business. The 2007 equine influenza outbreak in Australia resulted in huge losses for the horse-racing and associated industries. Hat makers, farriers, bookies, jockeys and ice-cream sellers all lost out while the disease spread rapidly through stables and livery yards across the south-east of the country.

Animal diseases are and will continue to be a significant burden to public health through direct zoonotic infections, such as rabies and brucellosis;

through the emergence of novel infectious agents from animals, such as types of influenza, the human immunodeficiency virus (HIV) and severe acute respiratory syndrome (SARS); and through food-borne pathogens of animal origin, such as *Campylobacter jejuni*, enterohemorrhagic *Escherichia coli* (EHEC) and salmonella. Estimates suggest that around 60% of human infectious diseases are zoonotic and that 75% of emerging human infectious diseases have an animal disease origin. The close interaction between humans, domestic and wild animals and the environment means that the human–animal–environment interface is an important source of new and emerging infectious disease.

ANIMAL PATHOGENS AS WEAPONS

Although animal pathogens have only rarely been used as bioweapons, they are an attractive option for bioterrorists. To date most biological attacks have employed animal pathogens and zoonoses such as anthrax, glanders and salmonella. Research into the weaponization of pathogens has also focused on animal and zoonotic agents. The perceived and real impact of certain animal pathogens, together with their relative free availability both in nature and in laboratory repositories—where they are held under varying levels of biosecurity—means that even poorly resourced groups may consider using them to wreak havoc. Unlike conventional weapons, pathogens can be easily transported undetected through security checks, and for more creative bioterrorists, malign research and development can be easily disguised. The fear that animal pathogens may be used by terrorists has certainly been heightened following high impact terror events, such as the attacks on the New York World Trade Centre and the anthrax letter attacks in the United States, in 2001.

The World Organisation for Animal Health (OIE) lists over 100 infectious animal diseases that are of the greatest concern to public and animal health, economies and that can spread rapidly across national borders. Because of their potential severity, all OIE member states are mandated to report occurrences of these diseases to the OIE, which warns the international community. The OIE list is updated by experts on a regular basis to include the latest threats, and includes all animal pathogens that might be potentially used as biological weapons.

Disease agents such as FMD are enzootic in many countries and are also held in laboratory repositories around the world. The cost of acquiring FMD infectious material and delivering it to susceptible animals is very small when compared to the damage caused by the deliberate introduction into disease free populations. Similarly, a small and contained release of a disease agent such as anthrax or the Ebola virus can invoke widespread anxiety and social disruption. Although the real risk from a number of these diseases may be small, even rumours can result in panic.

Biotechnology offers the possibility of manipulating pathogens to increase their effectiveness as weapons. Some of these technologies do not require highly specialized expertise or prohibitively expensive equipment. Monitoring threats from dual-use technology—technology that can be developed for peaceful, military or bioterror intentions—is particularly challenging.

NATURAL, DELIBERATE OR ACCIDENTAL RELEASE

Epidemiological investigations supported by laboratory characterization of disease agents are likely to elucidate the origin of a disease outbreak. Genetic sequence data are often able to provide clues about the geographical source of the agent, the possibility of laboratory origin or whether the agent has been genetically manipulated. The epidemiological investigation is also likely to identify the first cases, the likely source of infectious material and the pattern of further spread. Unusual events or multiple seemingly unconnected outbreaks may indicate something more sinister at work. When suspicion of malicious intent or accidental release is raised, the response goes beyond simply containing the disease and involves a criminal investigation.

It is critical to know about the possibility of bioterror involvement early so that the additional response can be mounted quickly, including raising an alert level to prevent or prepare for another release of agent. Therefore, in addition to detecting the disease outbreak early, it is important to characterize the agent and to carry out an epidemiological investigation.

The intergovernmental agencies responsible for the response to animal disease outbreaks are the Food and Agricultural Organization of the United Nations (FAO) and the OIE, with the World Health Organization (WHO)

when the disease is zoonotic. The UN agency responsible for investigating a suspected bioterror attacks is the United Nations Office for Disarmament Affairs (UNODA). UNODA also hosts the Implementation Support Unit, an international legal instrument to promote prevention and preparedness against bioterrorism.

Whether animal disease outbreaks are caused by natural events or by accidental or deliberate release, the mechanisms for disease detection, notification, containment and control are the same. These mechanisms are already in place to deal with the day-to-day more common risks posed by natural disease outbreaks. The capacity and strength of these mechanisms varies, however, from one country to another.

THE ROLE OF THE OIE

The OIE has the mandate to improve animal health, veterinary public health and animal welfare worldwide, and plays a key role at the intergovernmental level in mitigating risks posed by animal disease.

The organization was established in 1924 in response to outbreaks of rinderpest in Europe—a disease that had previously decimated livestock populations in large parts of Africa. Rinderpest highlighted the potentially devastating impacts of animal disease, and the 1920 outbreak in Belgium demonstrated the ease with which diseases spread internationally through unregulated trade. Since then the OIE has grown into a large organization of over 170 member states, focusing on global prevention and control of more than 100 diseases of terrestrial and aquatic animals, including new and emerging diseases.

The OIE shares a common interest with its partners the FAO and the WHO in reducing biological threats from animal diseases, including zoonoses, and fully supports the Biological Weapons Convention.

International standards and guidance

The OIE sets international standards for sanitary safety of trade in animals and animal products and for reducing and managing risks of animal disease in general. These standards are science-based measures to prevent the international spread of important animal diseases, including zoonoses,

many of which have bioterror potential. The standards, recognized by the World Trade Organization (WTO) as the international point of reference for animal health and control of zoonoses, support the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which states in its preamble that "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations".

The OIE standards are detailed in four texts (the Terrestrial and Aquatic Codes and the Terrestrial and Aquatic Manuals) and include guidance on:

- surveillance for the early detection of disease and declaration of disease freedom;
- rapid and accurate diagnosis of important animal diseases;
- manufacture of safe, effective and potent vaccines;
- specific risk-based standards on biosafety and biocontainment in veterinary laboratories and animal facilities;
- collection, transport, and safe keeping of biological materials;
- veterinary public-health and food safety;
- licensed importation of dangerous animal pathogens;
- disease-specific and general standards to prevent and control the national and international spread of animal disease, including zoonoses; and
- the quality of national veterinary services.

Aside from international standards, the OIE publishes numerous other guidance documents and recommendations to assist the international community in reducing risks from animal diseases.

If correctly implemented, OIE guidelines and recommendations maximize the ability of the international community and its members to protect themselves from the threat of a bioterrorist incident, as well as from natural and accidental releases, and reduce the impact on health, trade and economies if one should occur.

Disease intelligence

Risk identification is the first step in risk management and people are in a much better position to reduce risks when they are aware of them. For this reason the wide dissemination of up-to-date technical information about animal diseases, safe practices and the potential for the misuse or dual-use of pathogens is a basis for the global threat reduction of animal pathogens.

It is one of the OIE core objectives to disseminate scientific information which is gathered and assimilated by its network of world-leading scientists. The information is dispatched through scientific publications, scientific reviews, guidelines and standards, and technical disease cards. To increase the potential audience, much of this is freely available on the OIE website. Several publications address general principles, such as disease surveillance and control, risk assessment and laboratory biosecurity, whilst others address specific topics such as intentional biological disasters.

The OIE also acknowledges that to create sustainable scientific networks and safe scientific working culture, knowledge must be instilled at the grass roots. Of course, for biological threats this needs to include all life scientists, including veterinarians. Under its own mandate, the OIE is working to improve veterinary education worldwide. This includes developing core curricula.

Transparency of the disease situation

Early and accurate detection and immediate reporting of animal disease events to the international community underpin the ability to mount an effective international response. Delays in detection and response lessen the ability to contain the disease and lead to spiralling economic costs and greater health impacts.

The OIE is responsible for the transparency of the global animal disease situation, whilst the WHO is responsible for the transparency of diseases in humans. OIE member states have a legal obligation to report immediately OIE-listed diseases and new and emerging diseases in domestic and wild animals through the OIE World Animal Health Information System (WAHIS). This is then communicated to OIE member states through an electronic alert system and to the public through the World Animal Health Information Database (WAHID). This alert mechanism allows

the international community to respond rapidly to natural outbreaks or accidental or deliberate releases of disease agents by applying the science-based disease control measures laid out in the OIE Codes.

The OIE works closely with the OIE Delegate in each country to ensure that any data entered into the alert system and WAHID is properly validated. Although the OIE receives information about disease outbreaks from a number of sources, including its reference laboratory network, other international partners, the FAO/OIE/WHO Global Early Warning System (GLEWS) and from media rumours, it only publishes information that has been validated by the OIE Delegate.

Global animal disease transparency is not perfect and not all countries are 100% transparent all of the time. Concerns about economic losses through trade restrictions may lead to some underreporting or delays in reporting. However, a lack of transparency is counterproductive because trading partners soon hear about the disease outbreaks from other sources, leading to a loss of trust and credibility in non-transparent countries. It can take a long time for this trust to be restored, and in the meantime losses will be incurred as trade partners look to import animals and products from more reliable states.

Data supplied by the OIE demonstrates that there is an increasing trend in the number of immediate disease notifications made to the organization each year by its members. This increase in active reporting suggests that countries are becoming more transparent in reporting diseases to the OIE. The organization continues to advocate the importance of increasing transparency of the global animal health situation, including disease outbreaks, and details about implementation of surveillance and control programmes in different countries.

Disease tracking

With the revolution in electronic media communications, it is very difficult for states to successfully hide outbreaks of animal diseases. Rumours about disease outbreaks enhance the sensitivity of global disease surveillance. However, many also turn out to be untrue, and if the international community applies control measures based on false information, there will be needless losses in resources and credibility, and far-reaching economic impacts.

It is important that rumours about disease outbreaks are either confirmed or denied through a credible source, so that countries can be confident that they are basing important decisions on accurate information, and so that global animal disease data is not contaminated with poor data.

The OIE has joined forces with its partners the FAO and the WHO to form GLEWS, which allows the three organizations to combine the strengths of each of their own disease-tracking systems in one shared platform. Through GLEWS, the FAO, the OIE and the WHO confidentially share unofficial information about diseases that all three organizations have a common interest in—inevitably these are mostly zoonoses. The OIE works to validate information it receives through GLEWS about OIE-listed and emerging diseases through official channels.

Confirming disease

Confirmation of a disease outbreak depends on accurate detection and characterization of the disease agent. The OIE standards for diagnostic testing are laid out in the its manuals and provide guidance on globally harmonized and validated diagnostic procedures for OIE-listed diseases. Compliance with these standards will provide confidence that diagnostic test results are accurate, and global harmonization of testing procedures ensures quality and that results are comparable. OIE reference laboratories uphold these standards and play an important role in initial confirmation and further characterization of the disease agent—accuracy is critical at the onset of a disease outbreak. The implications of false negative as well as false positive laboratory results can be severe and wide ranging. As their name implies, reference laboratories are points of reference for states that lack the capacity and expertise to accurately detect and characterize the disease agent.

Global disease surveillance networks

The international reporting network of OIE Delegates is supported by more than 220 OIE reference laboratories and collaborating centres. Each reference laboratory specializes in a particular OIE-listed disease and operates to a mandate that includes providing confirmatory diagnostic testing and technical support to other OIE member states. The laboratories undertake to report positive diagnostic results for OIE-listed diseases to OIE headquarters, as well as to the OIE Delegate of the country from which

the sample originated. Because the reference laboratories are responsible for characterizing the disease agent and providing technical support to outbreak investigations, they are often the first to ascertain whether there is a suspicion of deliberate or accidental release.

Collectively, the OIE reference laboratories make up a global animal disease surveillance network, with the laboratories linked to each other at the global level and to a network of national laboratories at the regional level. Several disease-specific reference laboratories also exist, such as a FMD network and the OIE–FAO joint network of expertise on animal influenzas (OFFLU). These networks are important sources of information not only for the occurrence of disease outbreaks, but also for more technical information, including descriptive epidemiological, antigenic and genetic data.

Extending the network

The current distribution of the OIE network favours developed countries and the northern hemisphere. The OIE laboratory twinning programme aims to redress this imbalance by extending the network to provide better and more balanced geographical coverage, so that countries have more rapid and easier access to high quality diagnostic testing and expertise. Expertise is needed to ensure proper application of international standards and also to assist developing countries to engage in scientific debate on an even footing with others.

Each twinning project links an existing OIE reference laboratory or collaborating centre with a candidate laboratory, which leads to a transfer of knowledge and skills—allowing the candidate laboratory to develop capacity and expertise. Eventually the candidate laboratory will be able to provide support to other countries and in time may become an OIE reference laboratory or collaborating centre in its own right. Integral to all laboratory twinning projects is capacity-building for essential areas of expertise, such as quality assurance, and laboratory biosafety and biosecurity, thereby minimizing the risks of accidental release or theft of pathogens from containment facilities.

Laboratory capacity-building has multiple benefits that will reduce biological threats—including improvements in the capacity to early detect

disease, more effective biocontainment facilities and procedures, and more sustainable scientific networks.

Prevention is better than cure

Much can be done to prevent the accidental or deliberate release of dangerous animal pathogens from veterinary laboratories. Compliance with international standards on laboratory biosafety and biosecurity and proper laboratory management will go a long way to reducing these risks. The OIE is working closely with the WHO to promote good biosafety and biosecurity practices to be observed by veterinary as well as public-health laboratories.

Laboratory biosafety is about protecting the environment, humans and animals from pathogenic agents—ensuring that the pathogen remains in the laboratory. Laboratory biosecurity is about protecting the pathogen from people—preventing the pathogen from falling into the wrong hands.

Concerns have been raised about the possibility of scientists being lured into malicious research by terrorist groups, particularly in politically unstable countries, where the prospects for regular employment are poor. The risks will certainly be reduced when there are functional and sustainable scientific communities offering opportunities for employment and career development.

Veterinary services

Veterinary services stand on the front line in responding to animal disease threats, including from biological weapons. Early disease detection, timely reporting to the international community and implementation of an effective and proportionate response depend on having the appropriate technical expertise, resources and legislation under strong governance.

Regulation of research activities, including export and import of animal pathogens for research, is the responsibility of the national veterinary services. Such supervision reduces the possibilities for developing bioweapons through overt and dual-use technologies. States with weak veterinary services are much more vulnerable to the consequences arising from the misuse of animal pathogens, as well as natural disease outbreaks and the accidental release of pathogens.

A positive response from a veterinary service in one country reduces risks of disease outbreaks for many others in both the short and longer term. If the response is poor and animal diseases are allowed to become out of control, the risk of disease spreading to the international community rises. Whilst disease spread through trade can be mitigated by applying international trade standards, the risks of spread through illegal trade, wildlife, disease vectors and fomites can be harder to handle. Hence, the negative impacts of disease outbreaks in states with weak veterinary services are more likely to be felt beyond their national boundaries. These states may also make attractive targets for bioterrorists because they are more vulnerable, offering an opportunity to create larger and longer lasting impacts.

Appropriate and enforceable legislation is essential to enable veterinary services to implement effective disease surveillance and control, and regulate for biosafety and biosecurity. In many states this legislation is either inappropriate or non-existent.

The OIE provides tools to help its members to improve their veterinary services. The performance of veterinary services (PVS) tool is a mechanism for evaluating veterinary services on a number of critical core competencies, to identify gaps and deficiencies so that investments can be prioritized accordingly. A PVS mission is carried out in a country by a team of trained and certified experts—with all missions assessing the same criteria and working to the same methodology. The final PVS report can be used to attract donor funding and target investments to priority areas. The OIE urges states to make the PVS report public and to share it with donors to encourage effective and coordinated use of funds.

As a follow-up to the PVS missions, the OIE provides a PVS Gap Analysis, which puts figures on investments. PVS follow-up missions are also encouraged to monitor progress with capacity-building and to detect shifting investment priorities. The OIE has also launched the modernization of veterinary legislation initiative, which aims to help members develop effective veterinary legislation.

INTERNATIONAL COLLABORATION

The international response to a suspicion or actual deliberate release of a pathogen involves many actors. The scale of the response and actors involved depends on the circumstances.

The FAO, the OIE and the WHO are key international organizations, each with its own mandate and governance. The FAO and the OIE share common interests in the area of animal health and work with the WHO towards mitigating risks from disease emergence at the human-animal interface. The OIE and the WHO provide a legal framework for disease outbreak reporting in animal and public health, respectively.

Because international organizations operate primarily with their constituencies (for example, ministries of health or agriculture) at the national level and because their interactions at the international level tend to be complex, it is important for the three organizations to agree on how they work together towards common goals. A common strategy is agreed in formal agreements and implemented through specific mechanisms, such as GLEWS and collaboration between OFFLU and the WHO Global Influenza Programme.

An overarching strategy for the FAO and the OIE is implemented through the Global Framework for Progressive Control of Transboundary Animal Diseases (GF-TADs), which oversees specific programmes relating to the mandates of the FAO and the OIE and highlights areas of common interest where the two organizations can collaborate.

There has been high-profile public and political acceptance of the importance of the human-animal interface in emerging public-health threats, particularly as a response to the pandemic potential of avian influenza H5N1. In 2010 the FAO, the OIE and the WHO developed a tripartite concept note on sharing responsibilities to address health risk.[1] However, international technical collaboration in response to alleged accidental or deliberate release of a pathogen is perhaps best illustrated by citing a recent example.

In May 2009, when the world's attention was focused on a new strain of influenza H1N1, on its way to causing a pandemic, the WHO became aware of a pre-publication article suggesting the virus had a laboratory

origin. There was a need to quickly establish whether this was plausible. Within 24 hours a multidisciplinary team of influenza experts had been mobilized from WHO and OFFLU networks in response. The expert discussion established that the scientific basis for suggesting a laboratory origin was flawed, allowing the WHO to contact the author and refute the claim. If, on the other hand, the expert group had supported the technical content of the paper, then a wider response to investigate the source of the virus would have been triggered.

At the time, with little information about the origin or public-health implications of the virus and no widely available vaccine, the general public was particularly sensitive and open to suggestion. It is fair to say that if the international organizations had not been able to counter the paper's claims before publication, the media may have caused alarm by speculating about the possibility of malicious or accidental release of the pandemic H1N1 virus.

The example demonstrates effective collaboration between public- and animal-health sectors and the value of maintaining disease-specific networks and inter-agency links to inform decision-making when there is suspicion of accidental or deliberate release of pathogens. Minimal bureaucracy and the flexible nature of expert networks were key factors in delivering a rapid response.

Rapid response

The OIE does not attempt to maintain its expertise in-house, instead relying on a relatively small number of core staff and a large flexible global network of expertise held in its reference laboratories and collaborating centres around the world. This is an effective and efficient way of ensuring that expertise is kept up to date, while allowing the OIE to deploy its experts rapidly to provide technical assistance to any member state facing an animal disease crisis. It is part of the OIE reference laboratory mandate for experts to put themselves at the disposal of the OIE to provide this international support.

For joint missions the FAO and the OIE developed a mechanism for providing assistance to states in the face of animal disease emergencies: the Crisis Management Centre – Animal Health.

Collaboration with UNODA

UNODA promotes the goal of disarmament and non-proliferation, and the strengthening of the disarmament regimes for weapons of mass destruction, including nuclear, chemical and biological weapons. The Secretary-General has a mechanism to investigate allegations of biological weapon use following a request from a state where an alleged release has occurred. The investigation is similar to investigating a natural disease outbreak. The OIE and UNODA have an agreement to cooperate on such investigations and the OIE may be asked to nominate OIE experts with the necessary experience to participate in UNODA missions.

Global rinderpest eradication

In 2010 the world stood on the brink of rinderpest freedom. This milestone comes after decades of collaborative work culminating in the success of the Global Rinderpest Eradication Programme. The collaboration of international organizations, non-governmental organizations, and national veterinary services has been particularly active on the African continent.

Rinderpest will become only the second disease to be eradicated globally, after smallpox, which was declared eradicated in 1980. While this is a unique event given that it was one of the reasons for the establishment of the OIE, it will create a new and challenging situation. Once the disease is eradicated, global livestock and wildlife populations, having no natural immunity or vaccine history, will be particularly vulnerable to rinderpest. Because of this and its devastating effects, the agent is likely to be particularly attractive for bioterrorists. It is never possible to guarantee absolute disease freedom, so it will be important to keep stocks of reference agent strains, vaccine seed strains and ready-to-use vaccines in case there is a reoccurrence of the disease. This of course brings with it the risk that the agent is still available and might fall into the wrong hands. Proper storage to protect the agent from people with malicious intent and to protect animals from the agent will be essential. At the OIE General Session in May 2010 all OIE member states signed up to a resolution “Destruction, storage and confinement of rinderpest virus containing material and other actions required in view of global eradication of rinderpest”, which requires OIE member states to destroy or ensure safe storage under the appropriate containment condition any remaining rinderpest virus.

The FAO and the OIE are working together to put in place necessary contingency plans at international and national levels, including robust systems for rumour tracking and the ability to dispatch vaccines in case of emergency. Efforts will continue to maintain rinderpest in the education and training programme of veterinarians so that early diagnostics will remain possible even if the disease ceases to exist.

CONCLUSION

There is no doubt that animal pathogens offer the potential to be used as bioweapons, and "on paper" would appear to be an attractive option for certain terrorists. History has confirmed this with the few bioterror events involving animal disease agents and zoonoses. However, the more common risks for animal disease outbreaks are likely to come from natural events, through the evolution of existing pathogens and from the accidental releases of agents from laboratories. Whatever the route of infection into a susceptible animal population, the mechanisms for disease detection and containment are very similar. Investments in biothreat reduction will have multiple benefits and be more sustainable if they are targeted at existing disease control mechanisms which manage the omnipresent risk of natural disease outbreaks.

The effectiveness of an international response to any disease event is underpinned by early disease detection, characterization of the disease agent and transparent reporting to the international community. This requires rapid and accurate diagnostic testing. The global network of OIE reference laboratories provide valuable international technical support to achieve this and are often the first to be aware of suspicion of accidental or deliberate release.

Laboratory capacity-building programmes, such as OIE laboratory twinning, increase security against biological threats by strengthening global capacity to detect and react to them early, by improving secure storage of dangerous pathogens, and by building and sustaining international scientific communities that promote ethical and safe working practices.

Global security from animal diseases needs universally strong and well-governed veterinary services because a disease outbreak, deliberate release of a pathogen or a breach in laboratory biosecurity in one country

can threaten many others. Today many states suffer from weak and poorly governed veterinary services and there is an urgent need to address this.

International standards provide a basis for effective veterinary services. When applied properly they ensure that the impacts of animal disease, the risk of biological accidents and the risk of dangerous pathogens falling into the wrong hands are all kept to a minimum. Appropriate legislation is needed to ensure that these standards are implemented properly. A network of strengthened national veterinary services should thus be considered as invaluable common public goods that deserve sustained and concerted investment.

Coordination at the international level is essential to ensure efficiency and to avoid duplication. International mechanisms and platforms like GF-TADs and flexible networks such as OFFLU and GLEWS maximize the capacity to detect and respond to biological threats at the international level. Disease networks and informal exchanges of information also make up a very important component of disease intelligence.

Bioterror events are relatively uncommon and day-to-day preparedness against ordinary disease outbreaks offers the best and most sustainable protection against unusual, deliberate and accidental releases. To ensure that existing mechanisms also prevent the use or minimize the impact of bioterrorism, it is important that there is a strong understanding and awareness about the potential misuse or dual-use of animal pathogens among all life scientists, including veterinarians and associated bodies.

OIE remains committed to global biothreat reduction and collaboration with its international partners, including the FAO, the International Air Transport Association, UNODA and the WHO.

CHAPTER 27

INTERPOL TABLE-TOP EXERCISE BIOSHIELD AMERICAS 2010

Joris De Baerdemaeker

Senior officials from law enforcement and international organizations have taken part in a table-top exercise (TTX) organized by the International Criminal Police Organization (INTERPOL) simulating a global bioterrorism attack and its aftermath. In cooperation with the Netherlands National Coordinator for Counterterrorism (Nationaal Coördinator Terrorismebestrijding, NCTb), International Safety Research Inc. and INTERPOL Regional Bureau for South America, the BioShield Americas 2010 bioterrorism international TTX aimed to help focus joint understanding on the roles and responsibilities of police, health-care professionals and experts in response to a bioterrorism incident, as well as identifying possible gaps or redundancies so that lessons can be drawn from them.

The three-day event (14–16 June) brought together 42 senior representatives of public-health authorities, law enforcement (police and customs) and national crisis centres from 14 countries.[1] Participants in the workshop were faced with a fictional bioterror attack to assist them in identifying critical cooperation and coordination issues necessary to respond.

The event also included five experts and six representatives from the Pan American Health Organization (PAHO), the Organization of American States (OAS), the National Center for Preventive Programs and Disease Control (Mexico), the National Institute for Public Health and Environment Preparedness and Response Unit (the Netherlands), the US Federal Bureau of Investigation (FBI), and the World Customs Organization.

AIM OF EXERCISE BIOSHIELD AMERICAS

The aim of the exercise was to develop knowledge and share experiences and best practices in dealing with a bioterrorism event. This was done in a non-judgmental, relaxed environment. Participants, faced with an international bioterrorism scenario, were asked to define the likely actions and response that they would, could or should take to prevent the execution of the threat or to limit its consequences. Participants were specifically requested not to reveal confidential aspects of their national response plans. Neither were they asked to evaluate their plans and arrangements during the TTX. However, the goal was for the participants to be able to conduct an internal evaluation of their own arrangements after the TTX on the basis of the information gathered and discussions held.

AREAS OF DISCUSSION

The exercise focused on increasing the understanding of the inter-operability and communications issues and requirements between participating national and international organizations and government authorities, in response to a bioterrorism threat.

The scenario presented focused on event prevention and interdiction. The consequence management phase of a bioterrorism event was discussed, but it was not the focus of this exercise. The main topics of discussion were:

- planning and preparedness phase;
- protocols;
- agreements;
- training;
- detection and alert systems;
- response (as said this was not the focus of the exercise);
- pursuit (criminal case and investigation); and
- recovery (return to normal situation, decontamination issues).

INTRODUCTORY SESSIONS

In order to give the participants, who came from a variety of backgrounds and representing different agencies, a base on which to prepare their involvement in the exercise, they were presented with information on the capacities and support international and regional organizations could provide their countries in the case of an attack, as well as examples of best practices and of the importance of international cooperation between the states and international organizations. Presentations were provided by INTERPOL, focusing on its bioterrorism prevention programme as well as its role in connecting 188 member states in international police cooperation. INTERPOL also presented the current terrorist threat and use of chemical, biological, radiological and nuclear (CBRN) materials. The OAS presented their range of capacities and competencies in case of a terrorist-related event. The OAS also organizes TTXs for its member states to prepare for bioterrorist events.

Bioterrorism is not only a concern for law enforcement, but first and foremost a challenge to be tackled by public-health authorities. Diseases and health crises are dealt with on a global scale by the World Health Organization (WHO) and the PAHO—the regional WHO office for the American region—who presented on their specific roles. Importance was given to the socio-economic impact of global disease outbreaks and the importance of increasing the feeling of security of the general population through reassurance. While law enforcement and public health have different priorities and approaches to disease outbreaks, the work done is never in vain, as preparing for natural disasters can help prepare for bioterrorism attacks and vice versa.

At the national level a presentation was given on the Mexican H1N1 outbreak. The virus, first known as swine flu, quickly spread from person to person and caused the WHO to declare a pandemic. The Mexican health protection agency presented on the Mexican and international experience in coping with this new emerging disease. Some of the essential elements mentioned in the presentation critical to success are: adequate risk communication, stockpiling medicine and having up-to-date response plans. The co-organizer of this TTX, the NCTb, presented on their extensive efforts, including reaching out to private companies and scientists in a successful attempt to create a high-profile trusted community, sharing expertise, resources and intelligence to counter the CBRN threat.

Since resources are not infinite, select threats are chosen to focus on based on intelligence. The final goal is to produce an initiative which strengthens national security and at the same time is sustainable and profit-generating.

The bioterrorism threat cannot be properly understood without a basic understanding of how biological agents work and how they can be produced and used. This information was provided by the Dutch National Institute for Public Health and Environment Preparedness and Response Unit. One of the points that often cropped up during the session was the necessity of law enforcement and public health to work hand-in-glove. The FBI has developed a best practice of reaching out to the public-health community. In addition, indicators were explained and how these could lead law enforcement and public-health authorities to detect in an early or advanced stage the preparation or occurring of a biological attack. Joint public health–law enforcement cooperation, including interviews, is a prime example of how various aspects can be covered and information gleaned only through close cooperation of the two principal actors.

BEST PRACTICES

Based upon the discussions during the exercise, the following best practices and recommendations were presented:

Cooperation

The need was stressed among all groups for constant and continuous cooperation of all agencies involved in responding to a bioterrorist threat (police and customs, national crisis centres and public-health agencies). Working closely was determined as an essential factor in preventing a bioterrorist attack—as one group said, multidisciplinary groups should be created at the national and international level before something goes wrong, rather than after. Close cooperation between institutions as well as disciplines is called for in order for all agencies to be prepared. One of the best practices was formulated as increasing coordinated activity between different local, regional and global agencies involved in managing the crisis. Within this framework the need to find ways to exchange and share medical and police information was stressed. The recognition was made that ultimately, both law enforcement and public health are working

towards a common goal. Thus, on the level of response, joint coordinated investigations should become standard practice.

Media management

Another area where close work between different agencies is called for is media management. Not only must law enforcement and public-health authorities share information, but they must also jointly decide upon what information will reach the general public. As such, the joint elaboration of reports and the presentation of exact and precise information to the media are necessary. Furthermore, communication with the media should be pro-active in order to avoid panic and irresponsible or tendentious use of information.

RECOMMENDATIONS

All groups recognized that there is much to do on the level of preparedness at the national and regional level. There are actions to be taken specifically within the context of bioterrorism preparedness and prevention, but also general actions to be taken to boost states' response to naturally-occurring pandemics and other crisis situations:

1. First of all, most states should undertake a revision and implementation of national emergency plans in the area of terrorism and more specifically, bioterrorism.
2. Parallel to that, a review of the judicial framework in order to strengthen it in terrorism-related matters is necessary—at present in many countries it does not focus directly on terrorism or take it into account bioterrorism.
3. Similarly, many states may not be prepared with an appropriate post-attack contingency plan—such a plan should be in place, communicated and taught to all actors concerned so that they know how to react.
4. Once the legal framework and appropriate overall supervisory plan is in place, the personnel dealing with bioterrorist issues must be well-equipped and properly trained. Several groups specified the need for the training of personnel via seminars, international workshops and

courses. It was specifically stated that these training opportunities should be a frequent and permanent fixture, thus ensuring the knowledge in the ever-changing field of bioterrorism is up to date. One group also pointed out the need for bioterrorism programmes in police academies—many states in the region lack such basic awareness training. In this context, it is worthwhile mentioning that INTERPOL is working on a police training curriculum for national police academies. All training efforts, however, will fail if the proper equipment is lacking. Most groups stated the need for necessary equipment of counterterrorism teams. This is an area in which the problem of a lack of sufficient resources becomes evident. States which lack appropriate financial backing will have difficulty in implementing full-scale bioterrorism prevention measures—not due to lack of will, but due to pecuniary difficulties. This is precisely why these states should become more aware of opportunities available which call for no financial involvement.

5. It was suggested to that the operative capacity of response systems be boosted. In particular, public-health services, both in regard to equipment and the quantity and quality of human resources. In other areas, measures called for included strengthening the actions of migration and customs control, improving the capacity of laboratories, and increasing intelligence and investigative efforts. Further preventive action could be exercising even more control and applying physical security measures in high-profile, mass-audience events, or in conditions of isolation—especially in those places or opportunities selected as “targets” by terrorist organizations.

6. Even more specific and exact suggestions were given regarding media management of a bioterrorist crisis. First, the information presented should be true. Ambiguous expressions should be avoided, as well as any expressions which allow for multiple interpretations. Clarity of information is vital.

7. The public and the media should be regularly and periodically informed of the development of the situation in order to avoid creating situations of anxiety.

8. Participants suggested emphasizing the positive aspects of the message to be communicated. In the case of the scenario at hand, these included a low mortality rate, the existence of anti-virals,

and the possibility of cross-immunization by using a conventional vaccine, among others.

9. The recommendations for preparedness included establishing prevention services in high-profile events, which would shorten the response time, as well as having on hand reserves of vaccines and anti-virals and preparing areas and installations which would guarantee the isolation and quarantine of those infected.

10. With regards to networking, all participants agreed that the opportunity and possibility to meet and interact with other leaders and senior managers from their own country within the framework of the exercise was very valuable—senior leaders from different sectors from the same country had often not met before.

CONCLUSION

The recommendations from this exercise acknowledge that we all have a stake in ensuring that there is adequate national, regional and international capacity to prevent or respond to a bioterrorism attack. Law enforcement officers may be the first-responders at the scene of an attack, but depending on the mode of dispersal, it could just as easily be public health, medical or food safety officials who are at the frontline. Seamless coordination across all sectors and jurisdictions could literally mean the difference between life and death. Best practices should be developed on real case scenarios and discussed in exercises and seminars to topic alive. The INTERPOL bioterrorism prevention programme commits itself to keeping this momentum ongoing.

CHAPTER 28

INTERNATIONAL COORDINATION: RESPONDING TO THE USE OF BIOLOGICAL WEAPONS

Robin Coupland

The mandate of the International Committee of the Red Cross (ICRC) is to assist and protect victims of armed conflict and other situations of violence—including victims of chemical, biological and nuclear weapons. Yet the ICRC is at present largely unprepared to assist victims of these weapons. The ICRC decided to undertake a global risk assessment and study which capacities for victim assistance exist in this area.[1]

The Committee discovered that when it comes to mounting an international response, there was an assumption on the part of many agencies that work in this field that the ICRC would be prepared to mount a response. This chapter details the results of the study, the conclusions and how the findings might apply to the use or alleged use of biological weapons.

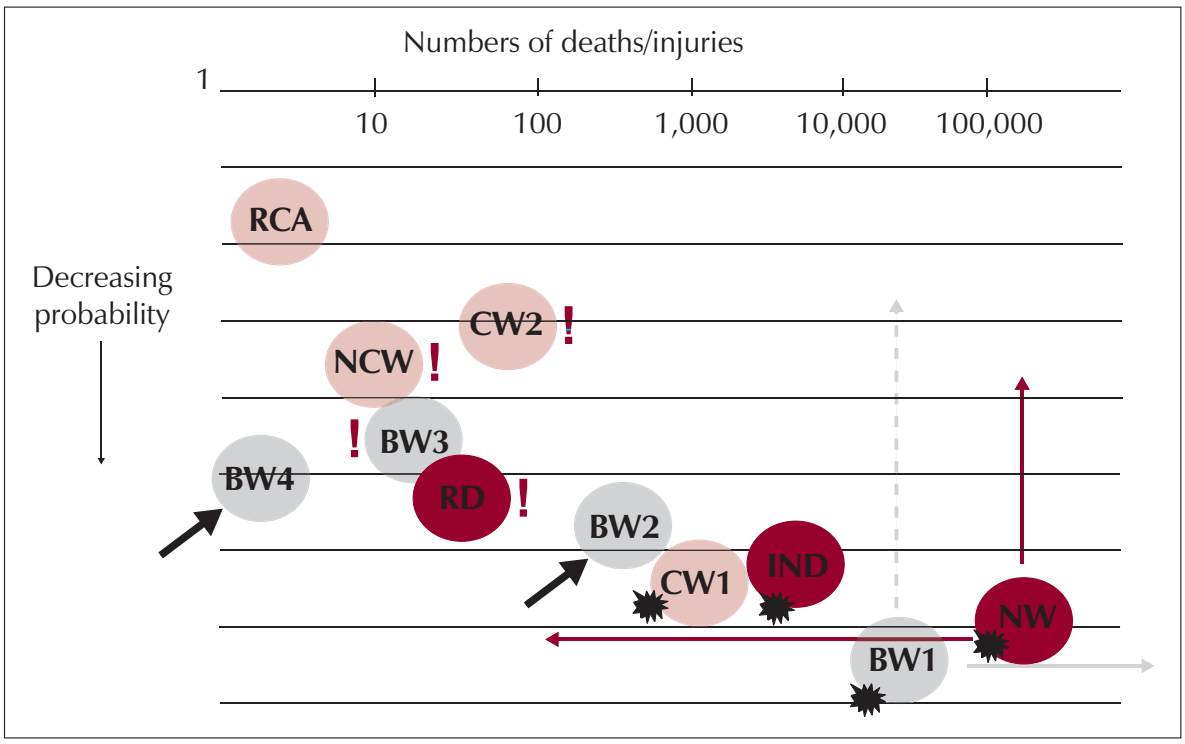
ASSESSING THE RISK

The study was based upon a generic risk assessment of the use of chemical, biological, radiological and nuclear (CBRN) weapons. With this risk assessment in mind, the ICRC examined its own current internal capacities, the capacities of other international organizations and certain national capacities. The Committee attempted to answer the question: "What is needed if the ICRC wishes to respond to the use of CBRN weapons in countries where we are operational?"

The generic risk assessment took into account the impact of the use of CBRN weapons in terms of the potential numbers of deaths and injuries that could result and the likelihood of such an event happening (see Figure

28.1). Both variables can change and our assessment reflected the context-specific nature of the risks. For example, the use of a nuclear weapon as an act of war would likely have a significant impact, with hundreds of thousands of victims. If such a weapon were used in remote regions such as out at sea or in the desert, then the potential impact decreases. As well as changes in impact, the likelihood of a nuclear weapon being used also changes. For example, if one state threatens another with nuclear weapons then the probability of such a weapon being used increases accordingly.

Figure 28.1 Risk of the use of CBRN weapons



With regards to biological weapons, the ICRC considered the intentional use of highly contagious agents, such as smallpox (biological weapon 1, BW1), as very unlikely but with the potential to affect millions of people. There is also the possibility of natural pandemics of such agents. The use of a contagious agent with lower levels of transmissibility, such as the causative organisms of cholera or the plague (BW2), was considered to be more likely but with less potential impact. The intentional use of non-contagious agents, such as the causative organisms of anthrax (BW3), was more likely to be used but with a lower number of deaths and injuries. The use of biological agents against plants or animals (BW4) would likely result in few deaths and injuries. Using this risk assessment, four low

probability–high impact risks were identified (marked in Figure 28.1 with small explosions):

- use of nuclear weapons in war (NW);
- chemical warfare (CW1);
- intentional use of a highly contagious biological agent (BW1); and
- use of an improvised nuclear device (IND).

Two risks were also identified that could most likely be dealt with through traditional public, animal and plant health measures (marked in Figure 28.1 with arrows):

- use of contagious but not highly transmissible biological agents (BW2); and
- use of biological agents against animals and plants (BW4).

The assistance response needed to deal with these risks would pose few surprises.

Examples of other agents used in the past (marked in Figure 28.1 with exclamation marks) include the causative organism of anthrax (BW3) or polonium (RD), the ad hoc use of chemical weapons, such as the Tokyo subway attack (CW2) or the use of a fentanyl derivative (NCW)—types of events which are most likely to take us by surprise. The assessment was that the ad hoc use of these agents was the most likely occurrence that could affect the ICRC during field operations and that this might be where the Committee should focus any response capacity it might develop.

QUESTIONING ASSUMPTIONS

The most important thing learned from the study was to emphasize that CBRN weapons are neither a single category nor represent a single risk. The relative risks of use can be refined. The ICRC recognized that opinion may differ on where each of the points labelled in Figure 28.1 should be. What is important is that CBRN risk can be refined. Furthermore, this risk assessment was based only on the *use* of CBRN weapons.

The risk assessment also highlighted the importance of identifying who will be responsible for victim assistance at an international level. Whilst there are many competent plans at the national level, it is not obvious to the ICRC how they will be translated into action at an international level. The ICRC concluded that a minimal response capacity within the organization might be feasible and it is in the process of developing this capacity. The Committee also concluded that before anything else is done, the primary consideration has to be the health and security of the staff bringing that assistance. The ICRC then might be able to assist some other victims and maintain other operations, such as visiting prisoners of war.

A range of other questions came to light:

- What about the threatened use of these agents?
- What about alleged use?
- What about the accidental release of CBRN weapon agents—for example, if a facility containing them were attacked with conventional weapons?
- What about a conventional attack on an industrial facility that uses some of these agents?

ALLEGED USE OF BIOLOGICAL WEAPONS

In order to justify an allegation of use, a disease outbreak will almost certainly have had to occur and an assessment made to establish the cause. This could be called the "first" diagnosis. This will likely have occurred as part of the public health response. Very rarely would such an assessment be an investigation as to how it was caused. As a result, the first diagnosis is unlikely to determine whether the origin is natural, accidental or deliberate, but is more likely to identify the causative agent and trace its epidemiology. It seems most probable that a response built upon the first diagnosis would be to provide humanitarian assistance and not to verify whether the use was intentional.

Being involved with cases involving allegations of the use of chemical or biological weapons carries its own dangers. It is possible that international agencies involved in assisting victims come into possession of dangerous information. For example, an ICRC convoy comes under attack on route

to assist victims of an alleged use of chemical weapons. Simultaneously, another state intercepts a message from the in-country team back to the ICRC headquarters regarding the chemical attack and presents it to the Security Council as evidence that chemical weapons have been used. This poses a distinct set of challenges for any organization that might be involved in such a response. These challenges and their ramifications should be explored now before it is necessary to deploy a field mission.

International organizations also have a duty of care towards their staff. As a result, ICRC current policy is that in the event of CBRN weapons being used, staff will be withdrawn from that context. This is not really compatible with the mandate to assist the victims of conflict, and we are currently grappling with this dilemma. To the best of the Committee's knowledge, the same guidelines apply to UN agencies. For those international organizations involved in a response to the alleged use of a biological weapon, the duty of care has practical ramifications. For example, each person that is being deployed has to be informed of the risks and has to be given the means to protect themselves. International organizations must be able to diminish the possibility of exposure and addressing the possible effects of exposure at the same time.

THE "SECOND" DIAGNOSIS: AN INTENTIONAL ACT?

Having established the agent, the next question is whether it was an intentional act. This can be thought of as a second diagnosis. There can often be a considerable time lag between the first and second diagnoses. According to publicly available information on the case of the anthrax letters in the United States, six weeks passed between the first death and confirmation that this was an intentional act. In the poisoning of salad bars in the United States by the Rajneeshee in the 1980s, there was a thirteen-month delay between the first person becoming sick and the final confirmation that this was an intentionally instigated outbreak.

There are also outstanding questions that pose distinct practical barriers to making a second diagnosis.

- Who should gather the information? Pertinent details can be found in both security and health sectors, from within and outside of government, and in the field.

- Who can access all the required information? It is not possible to simply walk into a hospital and demand to see medical records or photograph patients.
- Who concludes that it was an intentional act? Deciding whether an outbreak was instigated deliberately can have serious political ramifications.
- How is the information shared? Given the difficulties in gathering the relevant information, its sensitivity and the political ramifications, how will the information be fed into international processes, such as the investigative mechanism of the UN Secretary-General?
- Whose responsibility is it to announce to the public that an intentional act has taken place? Given the range of national and international actors involved in a response, it would be necessary to have a clear communications strategy in place to be followed.
- Who then assists in responding to the act and is that assistance to the state, the victims or the investigation? Both the nature and availability of such assistance can vary greatly.

CONCLUSION

The whole issue of responding to the alleged use of biological weapons requires a major reality check in the international domain. It is necessary to highlight the differences between a natural and an intentional outbreak, as they would be managed very differently because of the different political and security implications. Making a second diagnosis is not part of making the first diagnosis and there might be critical delay.

There should be more consideration as to what is meant by "assistance" both within relevant treaties and the international organizations concerned. There should be more consideration given to the critical and complex interface between public health and security. There has been some excellent work done at the national level on how public-health and security responses interact. At the international level, this interface will be much more complex. The ICRC final conclusion was that there should be very careful consideration of the duty of care that an employer carries when deploying staff to a situation where they might be exposed to a biological weapons agent.

CHAPTER 29

CASE STUDY: IMPLEMENTATION OF THE BIOLOGICAL WEAPONS CONVENTION IN KENYA

Austin Ochieng Aluoch and Maurice Owuor Ope

Kenya signed and ratified the Biological Weapons Convention (BWC) on 7 January 1976 and is currently focused on implementing the following (summarized) Articles of the BWC:

- Article 4: state parties should take any national measures necessary to implement the provisions of the BWC domestically;
- Article 5: state parties should consult bilaterally and multilaterally to solve any problems with the implementation of the BWC;
- Article 9: each state party to the BWC will also recognize and adhere to the Chemical Weapons Convention; and
- Article 10: to do all of the above in a way that encourages the peaceful uses of biological science and technology and participate in meetings organized to strengthen the BWC.

NATIONAL IMPLEMENTATION

The Government of Kenya recognized the growing threat of biological agents that may be misused to cause devastating epidemics or develop biological weapons. Consequently, Kenya signed and ratified the BWC and adopted Security Council resolution 1540[1] on the non-proliferation of weapons of mass destruction.

The Government of Kenya also recognized that coordination of biosecurity and oversight of dual-use life science research is vital in mitigation against a potential bioterror attack. In response, the National Biological and Toxin Weapons Committee (NBTWC) was put in place not only to meet Kenya's

international obligations as state party to the BWC, but also to develop a comprehensive policy and legal framework for national biosecurity.

The NBTWC

The national focal point for the BWC was the Ministry of Foreign Affairs, which sent representatives to the BWC Intersessional Process—the Meeting of Experts and the Meeting of States Parties—held in August and December, respectively. After the December 2008 Meeting of Experts, the need to have the scientific community involved in BWC matters was realized. Consequently, Kenya's national focal point on the BWC was changed in 2009 to the National Council for Science and Technology (NCST), which is a semi-autonomous entity and is housed under the Ministry of Higher Education, Science and Technology. The NCST formed the NBTWC in 2009.[2]

The terms of reference of the NBTWC were to draft a biosecurity policy and bill, represent Kenya at the Meeting of Experts and Meeting of States Parties and coordinate the submission of confidence-building measure (CBM) forms. Since its inception the NBTWC has been involved in a number of activities:

- completed drafting of the biosecurity policy, which is as of January 2011 under review by stakeholders;
- Kenya submitted the CBM forms for the first time in 2010;
- formed the local organizing committee for the UN 1540 African Regional Workshop on Biosafety and Biosecurity, held in Nairobi, 2–4 February 2010;
- sent representatives who gave statements and presentations to the BWC Meeting of Experts and Meeting of States Parties in 2010; and
- attended a regional workshop on the national implementation of the BWC, in Abuja, 25–27 October 2010.

Integrated Disease Surveillance and Response strategy

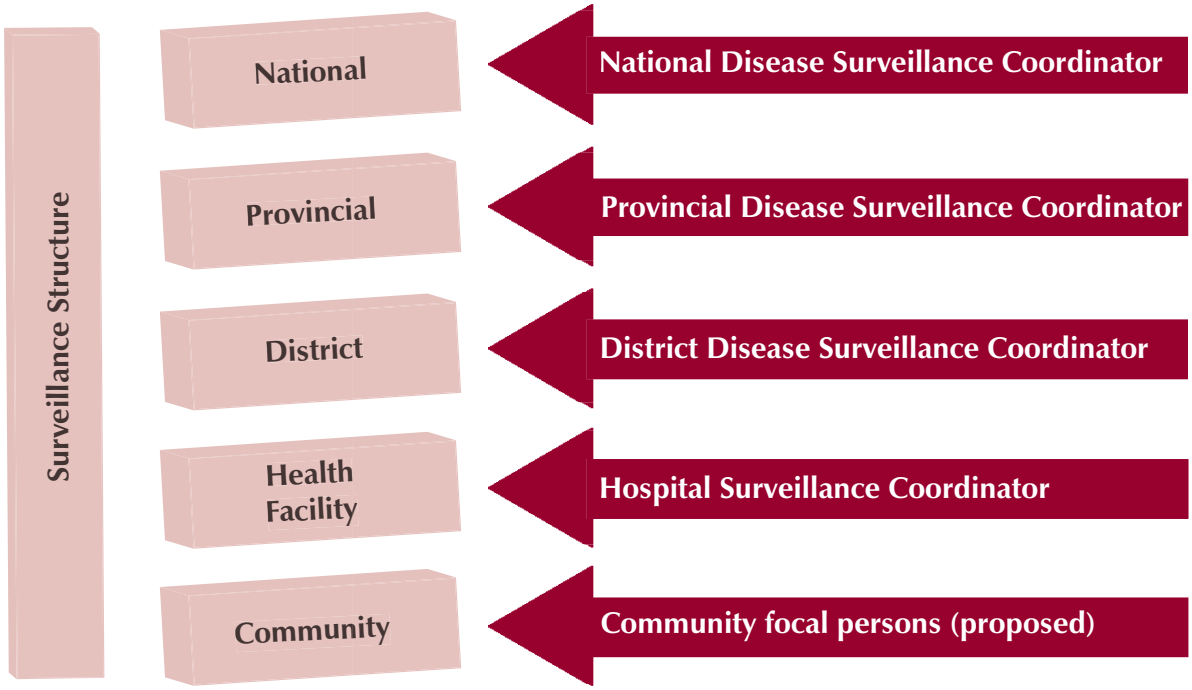
Communicable diseases continue to be a major cause of morbidity and mortality in Kenya. The majority of these diseases are preventable, although several factors—including environmental, social and economical

determinants—can hamper their prevention and control. The Government of Kenya recognizes the significance of good preparedness and early response to epidemics in order to reduce the health and economic impacts of these diseases. The source of the disease—be it intentional or natural—becomes secondary. The important parameters are mainly the ability to detect that an unusual event has occurred, taking medical measures, such as treating patients in a safe and effective manner, decontamination procedures, quarantine and evacuation. Therefore, a state that is well-prepared for a natural disease attack will also be prepared for a bioterror attack. Recognizing that other public events of international concern may occur and that there is need to control them with minimal effects on trade and travel, Kenya signed the World Health Organization Integrated Health Regulations (IHR) in 2005 and has been implementing the Integrated Disease Surveillance and Response (IDSR) strategy since 1998. Kenya's disease surveillance structure is shown in Figure 29.1. Kenya has identified 18 priority diseases and established reporting mechanisms and timelines. The priority diseases are:

- epidemic prone diseases: cholera, dysentery, measles, meningococcal meningitis, plague, typhoid fever, yellow fever and other viral haemorrhagic fevers;
- diseases earmarked for eradication: dracunculiasis, leprosy, neonatal tetanus and poliomyelitis; and
- diseases of public-health importance: new AIDS cases, childhood diarrhoea, childhood pneumonia, malaria, sexually transmitted infections and tuberculosis.

All the epidemic prone diseases, malaria, neonatal tetanus and poliomyelitis are reported on a weekly basis.

Figure 29.1 Kenya's disease surveillance structure



The current focus of the IDSR in Kenya is to strengthen district-level surveillance and response, involve communities in surveillance through the community strategy, minimize duplication in reporting, share resources among disease control programmes and translate surveillance and laboratory data into public-health action.

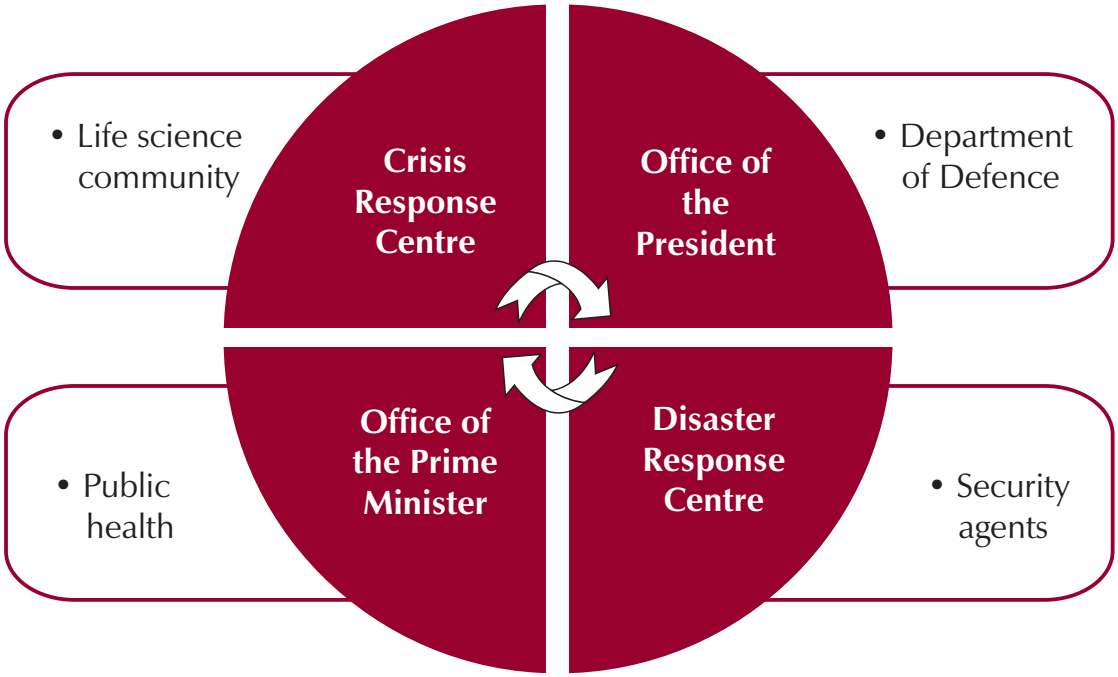
In view of the increase in non-communicable and zoonotic diseases and the effect of climate change on disease profile and increased migration, Kenya began the process of revising its IDSR technical guidelines in January 2011 in order to take these changes into account and to align them to the IHR.

BIOSECURITY RESPONSE

Although coordinating the implementation of the BWC in Kenya rests with the NCST (and the NBTWC), in the event of a bioterror attack, both the Offices of the Prime Minister and the President play a central role in coordination, depending on the magnitude of the attack. A cabinet subcommittee on crisis would take the lead. The secretariat of this

subcommittee is at the Crisis Response Centre, under the office of the Prime Minister. The Crisis Response Centre coordinates all partners and stakeholders involved in the response. The Disaster Operation Centre under the Office of the President, which is the rapid response unit, coordinates recovery and rescue efforts. The NBTWC works in tandem with these branches of government to achieve its objectives in mitigating the response—for example, providing a list of experts to identify an unknown pathogen.

Figure 29.2 Collaboration for an effective response to a bioterror attack



The response takes two forms: the health response, which involves measures to mitigate and control the effects of the attack; and the security response, which investigates the origins of the attack and prosecute those responsible. However, security agents, whose specialty may not be in identification and handling of biological agents, need to work with the life science research community. Therefore, for an effective response, collaboration and coordination between the public-health authorities, security agents and the life science community is essential. The NBTWC and NCST can facilitate the necessary expertise needed from the life science research community from their database of experts.

HEALTH RESPONSE

The health response is coordinated by the Ministry of Public Health and Sanitation, whose director takes lead through the Division of Disease Surveillance and Response. The response depends on the form of the attack. If the attack is overt and the disease has a short incubation period, the affected area and people may be localized. If the attack is covert and the disease has a long incubation period, the disease will appear in different parts of the country at different times, so concerted efforts to identify and trace those affected take priority.

In case of an attack with an agent that is not on the priority list, identification of the agent takes precedence. This requires collaboration with life sciences researchers locally or internationally. New reporting mechanism are also necessary—for example, it is required that the new disease is reported within 24 hours. In addition, a different method of transmitting data to the usual ones is required. It may be necessary to have these reports communicated to a designated person on 24-hour standby. Moreover, additional reporting sources may be required.

Challenges

For an effective health response:

- There is need for the establishment of more biosafety level 3 (BSL 3) laboratories, which can be used to identify pathogens that may not be in Kenya's IDSR priority list or other zoonotic diseases. The need for capacity-building in the national veterinary services is imperative, since 80% of pathogenic agents that can potentially be used in bioterrorism are zoonotic—for example, *Bacillus anthracis*. Biosecurity standards for laboratories set by the World Organisation for Animal Health need to be adopted.
- Kenya lacks a clear mechanism of ensuring that the isolation and quarantine orders are implemented. Quarantine facilities need to be established at the national and district level (for example, district hospitals) and at entry points (borders and airports).
- Health workers in both public-health facilities and private require training in disaster management because they are the first responders in the event of a bioterror attack.

SECURITY RESPONSE

The National Command Center, which is under the Office of the President, is responsible for the security response. The security response involves the police and other security agents, who investigate, apprehend and prosecute the perpetrators—especially if it is thought that an epidemic has occurred as a result of criminal activities. If the attack were a threat to national security, the National Security Intelligence Service and military would also be called in to assist in the investigations and response. The President, in his capacity as the commander-in-chief of the armed forces would provide leadership in the response.

The National Disaster Operation Centre, which is under the Office of the President would coordinate quick multisectoral response and rescue efforts.

Challenges

For an effective security response:

- Security agents need to be trained on biosecurity, biotechnology and counter bioterrorism and disaster management.
- There are no clear lines of communication between the life sciences community and security agents. The life sciences community would provide the expertise needed to identify new pathogens and supporting evidence to aide in the prosecution of bioterror perpetrators by security agents. The NBTWC and NCST, which would have the list of life science experts, should be relocated to the Office of the President for effective coordination of the life sciences community during a crisis.
- The NBTWC and NCST need to establish clear links with the National Command Center.
- There is a need to stockpile personal protection equipment for first responders.

LIFE SCIENCES COMMUNITY

The threat of bioterrorism is more prevalent because of the proliferation of technology and scientific progress in biochemistry, biotechnology and the life sciences. Current research programmes in Kenya are in universities, government laboratories and private biotechnology companies. These include experiments directed toward discovering vaccines, new antibiotics for both bacterial and fungal diseases, new sources of genes to protect crops against pests and diseases, and treatments for diabetes, malaria, and strokes. The knowledge and awareness of the potential for misuse of biological agents knowledge (dual-use dilemma) varies widely among the life sciences community in Kenya.

Challenges

For an effective response by the life sciences community:

- The awareness of the life sciences community on biosecurity and dual-use dilemma issues is insufficient. There is a need for dual-use biosecurity education for life scientists.
- Early biological agent detection equipment is in short supply for first responders. Collaborative research for the development or technology transfer of biological agent early detection equipment should be initiated.
- There is no system of identification and oversight of dual-use research and research laboratories. An oversight mechanism should be developed. This could be done by the NBTWC and NCST. However, the oversight mechanism should not stifle the free flow of scientific information and the potential gains of benign life sciences research that may lead to solutions to our current challenges.
- There is no database of expertise for life science researchers. This should also be established by the NBTWC and NCST.

CHAPTER 30

VIEWS FROM THE FIELD I: REGIONAL INFECTIOUS DISEASE SURVEILLANCE NETWORKING

Louise Gresham and Leslie Pray

The importance of building infectious disease capacity—the ability to detect and respond to infectious disease threats at their origin before they have a chance to spread—has emerged as a key theme in both public-health and national security arenas, with experts and officials in both fields grappling with many of the same issues. In public health the revised International Health Regulations (IHR)[1] provide a long overdue international legal mechanism for global governance of infectious disease surveillance, requiring all World Health Organization (WHO) member states to develop and strengthen core surveillance capacities by 2012. However, many experts have expressed concern that full implementation of the IHR is seriously challenged by the reality that many states do not have the necessary resources, and in some cases political will, to build the mandated capacity, and that many states will need more guidance than the WHO has provided so far.[2] This raises the question of how will member states with limited resources garner the necessary tools to increase their surveillance capacities to meet IHR demands. Coincidentally, among other objectives the 2009 Intersessional Process of the Biological Weapons Convention (BWC) focused on the importance of promoting capacity in disease surveillance. Recognizing the connection between the objectives of the BWC and global public-health security, states parties agreed during the Meeting of States Parties in December that building infectious disease surveillance capacity "would directly support the objectives of the Convention" and, conversely, that BWC-related capacity-building activities "could also contribute to the fulfilment of their other respective international obligations and agreements, such as the revised International Health Regulations (2005)".[3] But again, a key question remains: How can and should states parties work together to promote capacity-building? It is proposed here that trust-based regional infectious surveillance networks, several of which have emerged over the past decade, may provide at least

a partial solution to the capacity-building challenges of both the IHR 2005 and the 2009 Intersessional Process.

THE MEKONG BASIN DISEASE SURVEILLANCE NETWORK

In 1999 delegates from the ministries of health in six states in the Mekong Basin—Cambodia, the Yunnan and Guangxi provinces of China, the Lao People's Democratic Republic, Myanmar, Viet Nam and Thailand—agreed to collaborate in an innovative disease surveillance network to strengthen national and regional capacities to rapidly detect and respond to infectious disease outbreaks. Two years later the ministers of health of the six states formalized the Mekong Basin Disease Surveillance (MBDS) network. Established with the support of the Rockefeller Foundation and the WHO, the MBDS has also received support from the Agence française de développement (AfD), the United States Centers for Disease Control and Prevention (CDC), the Google Foundation and the Nuclear Threat Initiative's Global Health Security Initiative (GHSI). The MBDS network has helped its six member states to build surveillance capacity at both national and provincial levels through regular cross-border information exchanges and table-top disaster preparedness exercises, health personnel trainings and other cross-border cooperative activities. The partnership proved its worth in 2007, when MBDS networking helped to successfully contain cholera outbreaks on the Thailand-Myanmar and Thailand-Laos borders. It demonstrated its value again that same year when MBDS networking contributed to a successful joint Thailand-Laos investigation following the first human case of H5N1, in the Lao People's Democratic Republic.

The key to the success of regional networking is trust. Microbes know no borders, and managing infectious disease outbreaks often requires dealing with difficult cross-border situations. Trust empowers experts and officials from different countries to manage those difficult situations. The MBDS network is in effect a network of trust-based relationships among public-health experts and officials that developed over time and which did not exist before the network, some 10 years ago. When the network initially formed, there was very little cross-border exchange—experts and officials from the different countries failed to travel and meet with each other on a regular basis—if at all—and regional collaboration comprised mostly of impersonal top-down business being conducted by two separate WHO offices. The member countries of the MBDS belong to two different WHO

regions: Cambodia, China, the Lao People's Democratic Republic and Viet Nam belong to the WHO Western Pacific region, and Myanmar and Thailand belong to the South-East Asia region. While regional networks can neither replace the WHO or government discussions—nor should they—they create ways for individuals to meet in person as events unfold, and to conduct regional surveillance with the speed and efficiency that no other organization can achieve.

THE MIDDLE EAST CONSORTIUM ON INFECTIOUS DISEASE SURVEILLANCE

The Middle East Consortium on Infectious Disease Surveillance (MECIDS) is another successful trust-based partnership—between veterinary and public-health experts and ministry of health officials in Israel, Jordan and the Palestinian Authority.[4] The MECIDS was established in 2003 with the support of the GHSI and another non-governmental organization, Search for Common Ground, and it has received additional support from Becton Dickinson and Company, IBM, the World Bank and the WHO. Through regular cross-border information sharing and training, the development of shared emergency response protocols, and other coordinated cross-border activities, the regional network of professional and personal relationships that has developed over time has played an instrumental role in detecting mumps and salmonella outbreaks and containing the spread of H5N1 and H1N1.

Together, the MBDS and MECIDS networks demonstrate that animal and human health experts and officials from neighbouring countries can work together to build regional and national surveillance capacities and manage even the most difficult cross-border emergency outbreaks. While the early growth of both networks relied on external funding, it cannot be overemphasized that the achievements of the networks stem from the trust-based relationships that each network has fostered over time. The MBDS and the MECIDS rely on social capital in a way that most other infectious disease surveillance systems do not.

THE SOUTHERN AFRICAN CENTRE FOR INFECTIOUS DISEASE SURVEILLANCE

Recognizing the critical role that social capital and trust-based cross-border surveillance plays in the prevention of regional and worldwide epidemics, several additional groups of states have recently created or are in the process of creating similar regional networks for infectious disease surveillance. One of the latest networks is the Southern African Centre for Infectious Disease Surveillance (SACIDS). Established in 2009, SACIDS is a One Health consortium of medical and veterinary experts in the Democratic Republic of Congo, Mozambique, South Africa, Tanzania and Zambia.[5] While SACIDS has yet to be tested with any potential regional outbreaks, as the MBDS and MECIDS have been, in its first year of existence alone SACIDS established a governance structure, founded national centres for infectious disease surveillance in its member states to establish a voice at the national level, and conducted a variety of research projects on priority diseases in the region. SACIDS has received support from the GHSI, the Google Foundation, the Rockefeller Foundation and the Wellcome Trust. The GHSI is also exploring development of a new, trust-based, regional infectious disease surveillance network in South Asia, which would initially involve Bangladesh, India and Pakistan.

Meeting International Health Regulations obligations

While the IHR provide a necessary framework for international collaboration in infectious disease prevention and control and represent a radical shift to a more transparent and cooperative approach to achieving global health security, giving the WHO a pre-emptive power that it did not have under the original IHR from 1969, many experts agree that full implementation of IHR will require addressing several significant concerns. The lack of financial resources to increase surveillance capacity is indicated as being the greatest overall challenge, and the task of turning the vision of IHR into reality is "daunting".[6] Regional networks relieve some of this weight with their focus on collective capacity-building. Instead of each state working in isolation to develop its legally mandated core capacities, networks provide a means for member states to maximize the use of shared resources and minimize duplication of efforts—for example, by conducting joint training and developing harmonized infectious disease threat detection and response protocols. Resource limited or not, many

states may need more technical guidance in fulfilling their IHR 2005 obligations:

> The IHR does not tell nations how to conduct surveillance but rather tells them what results surveillance should produce ... National governments would benefit from having explicit standards and guidelines to support the infrastructural development of their national infectious disease surveillance systems. This is especially important for developing countries that have limited infrastructural capacity and that may need support to establish these systems for the first time.[7]

Again, networks provide a means for member states to assist each other in manoeuvering the IHR landscape. They also provide a novel means for member states to interact with the WHO. For example, in 2007 MECIDS members and the WHO convened a workshop on how to implement the IHR in the event of an influenza pandemic.[8]

Arguably, the greatest challenge to building national infectious disease surveillance capacity is building good working relationships between surveillance experts and officials in neighbouring countries. Because infectious diseases know no borders and because many infectious disease outbreaks demand cross-border responses, building national surveillance capacity goes hand-in-hand with establishing and fostering those relationships. In the event of a cross-border outbreak, even if two neighbouring states have good national capacities to detect and respond to infectious disease threats within their respective borders, they will have an extraordinarily difficult time containing the outbreak if transnational cooperation is weak or non-existent and if there is no system in place for real-time responses to events as they are occurring. Because trust-based regional networks foster good working relationships between experts and officials in neighbouring countries, they provide a powerful new tool for member states to use to overcome what is arguably the greatest challenge.

STRENGTHENING THE BWC

Trust-based regional networks also provide a powerful new tool for states parties to use to work together in implementing the various capacity-building actions proposed during the 2009 Intersessional Process. Reflecting a dramatic departure from the past, when natural and deliberate biological threats were addressed separately, a key feature of the 2009

Intersessional Process was widespread recognition that capacity-building in infectious disease surveillance advances both global public health and the security interests of states parties. As such, a key goal of the 2009 Meeting of Experts, which was held in Geneva from 24–28 August 2009, was to discuss effective action for promoting capacity-building in the fields of disease surveillance, detection, diagnosis and containment of infectious diseases. The 2009 Meeting of States Parties, which was held in Geneva from 7–11 December 2009, discussed and further developed the work of the Meeting of Experts. While intersessional meetings are not expected to arrive at consensus conclusions, many of the proposals for action put forth at the December meeting were based on the agreed premise that building surveillance capacity would directly support the objectives of the BWC. For example, the report of the Meeting of States Parties states: "States Parties agreed on the value of improving integration of capacity-building activities so that scarce resources are used effectively to combat disease irrespective of its cause, including through: ensuring effective communication and coordination among human, animal and plant health sectors".[9] As with the IHR 2005, the proposed action provides information about what to do but not how to do it. With its emphasis on an integrated veterinary–wildlife–human health approach (the One Health approach), regional networks provide ideal forums for developing relevant strategies to ensure effective communication and coordination across the veterinary, wildlife and public-health sectors.

The report also states that: "States Parties agreed on the value of ensuring the sustainability of capacity building in the fields of disease surveillance ... [and] ensuring ownership by the receiving country and the involvement of all relevant stakeholders".[10] The MBDS, the MECIDS and other trust-based, regional infectious disease surveillance networks are autonomous, self-sustaining units and, as such, create a novel mechanism for collective capacity-building that is different than other strategies being proposed, such as what the US government has proposed—a key goal of the Obama administration's National Strategy for Countering Biological Threats, which was released just prior to the December Meeting of States Parties. As with the BWC 2009 Intersessional Process, the strategy reflects a dramatic departure from past policy by addressing the full spectrum of biological threats—natural, deliberate and accidental. A key assumption of the strategy is that "the rapid detection and containment of, and response to, serious infectious disease outbreaks—whether of natural, accidental, or deliberate origin—advances both the health of populations and the security

interests of States".[11] A key goal of the strategy is to promote global health security by "building global capacity for disease surveillance, detection, diagnosis, and reporting" and "improving international capacity against infectious diseases".[12] To reach this goal, the strategy calls for assisting partner states and regions in their efforts to comply with the IHR and other reporting guidelines (animal and agricultural disease guidelines). At the Meeting of States Parties in December 2009, US Under Secretary of State for Arms Control and International Security, Ellen Tauscher, announced that the CDC would be establishing the first WHO collaborating center to assist partner states in implementing the revised IHR.[13] It remains to be seen how differences between a regional network approach, a CDC-facilitated approach, and other approaches compare and complement each other. Meanwhile, the report of the 2009 Meeting of States Parties notes: "the Seventh Review Conference could consider current and future proposals on means of better identifying needs [and] overcoming challenges to capacity-building".[14] It would be prudent to include regional infectious disease surveillance networks in that discussion.

CONCLUSION

The IHR and 2009 Intersessional Process share similar goals with respect to infectious disease surveillance capacity-building. But questions and challenges remain as to how WHO member states and BWC states parties—particularly those with limited resources—will be able to actually increase infectious disease surveillance capacity to the extent necessary. Regional networking provides a powerful opportunity to help states increase their surveillance capacities and, in so doing, simultaneously meet their (legally binding) international obligations under the IHR and implement (non-binding) actions proposed during the 2009 Intersessional Process of the BWC.

CHAPTER 31

VIEWS FROM THE FIELD II: THE INTERNATIONALIZATION OF MICROBIAL FORENSICS TO ADVANCE GLOBAL BIOSECURITY

Randall Murch

Now is the appropriate time to engage in a purposeful global debate for an internationally-governed, high-quality, microbial forensic capability to add value to the global biosecurity "kit", including other measures such as:

- international agreements;
- cooperative public-health and law enforcement programmes;
- improved biosafety and biosecurity practices;
- broad disease biosurveillance programmes;
- advanced diagnostics;
- improvements to and increasing the availability of vaccines;
- therapeutics; and
- prophylactics.

However, for various reasons perpetrators can exploit vulnerabilities and breach these defenses. Thus, to further "raise the bar" against the malicious use of infectious disease agents and certain biomolecules, perpetrators should be held at risk and accountable through improved and more agile investigation and attribution capabilities supported by science. A credible microbial forensic capability could also contribute to deterrence. Microbial forensics and the emerging forensic investigative capabilities resident in the US government and very recently presenting in other states, could be the foundation from which to construct, evolve and sustain an international forensic capability of this sort. This could be similar to what exists to support UN inspections and the investigation of the development, possession, use

and proliferation of chemical, nuclear and radiological weapons and their components. An end-to-end, multidimensional, international microbial forensics capability is envisioned.

If an attack involving biological agents were to occur, it is reasonable to expect that the following questions would need to be answered:

- What is or was it?
- How bad are the effects and how much worse will it get?
- Who did it?
- Did it come from a laboratory we know about?
- Will there be more attacks?
- What are we and the states involved doing about it?
- What can we know when and with what confidence?

Answers to several of these questions would be sought through intelligence, law enforcement investigation, public health and science until sufficient information had been gathered and vetted to support decision-making. If the event in question were suspected or determined to have been deliberate or accidental, among the highest priorities would be to determine who was responsible so that the appropriate measures could be taken.

While consequence managers and responders would be contending with the event to mitigate the effects and protect against further damage, the crisis managers, including law enforcement, intelligence and national security organizations, would be using all available means to answer the following questions from their perspectives and identify those involved, in preparation for legal or policy decisions and follow-on actions:

- Did an event of interest occur?
- What happened?
- How did it occur?
- Where did it occur?
- Why did it occur?

- Who was involved?
- Who was responsible?
- What evidence exists?
- What does it tell us?
- Do links exist to persons, places and things?
- How reliable and credible is the evidence?
- What are alternative explanations for the evidence?
- Will we be able to defend our conclusions, recommendations and actions that result from the evidence?

FORENSIC SCIENCE

Forensic science can help inform both the leaders' questions, as well as those posed and refined during the investigative and intelligence processes, through extracting relevant information from physical evidence. Forensic science is the domain that would be called upon, as an "independent witness", beginning very early during the investigation and intelligence gathering, as well as for the "prosecution", whether for legal or policy decision purposes. Forensic science can be formally defined as:

> The identification and characterization of physical evidence to determine its relevance to persons, places, associated actions, tools, methods, processes, intentions and plans related to an event of interest.

Classical (or traditional) forensic science disciplines include:

- human DNA analysis;
- chemistry and toxicology (inks, paints, cosmetics, drugs and poisons);
- materials science (composition and physical characteristics, manufacturing);
- trace evidence (hair and fiber);
- impression and pattern (fingerprint, document, shoeprint and tire tread);

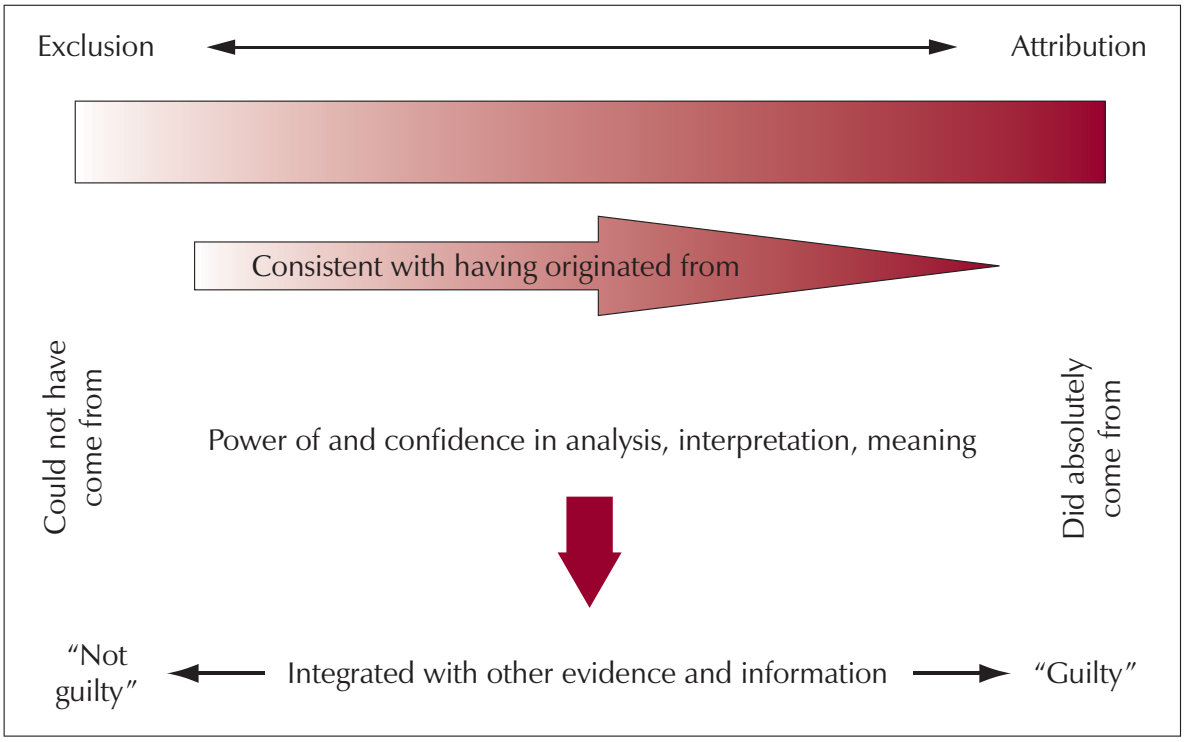
- engineering (failure analysis, accident reconstruction);
- digital forensics (computers, digital media and personal communication devices); and
- forensic medicine and pathology (manner and cause of death and injury).

The capability and acceptance of the science, and its admissibility, use and scrutiny in legal proceedings vary from state to state—but there is no known formalized process for scrutinizing forensic evidence for policy decision purposes.

Forensic analysis and interpretation can provide useful investigative and criminal jurisprudence information and can lead to "attribution" or the assignment of the source of evidentiary samples. This in turn leads to decisions pertaining to guilt or culpability (Who did it? Who is involved?). The definition of attribution varies between science, law and policy—with science being the most conservative (that is, having originated from one source to the exclusion of all other sources to a high degree of scientific certainty). Even with the most definitive forensic analyses, it is rare that science alone, even with a preponderance of scientific evidence, will suffice as the sole source of information that answers any or all of the questions listed above, or leads to decisions of guilt or culpability, to an acceptable level of sufficiency and certainty, in legal or policy terms.

The Forensic Continuum (see Figure 31.1) conveys that forensic analyses can contribute to determining whether or not a sample from a questioned source ("evidentiary samples") could have originated from a known source. Exclusion (could not have originated from) can be a straightforward determination when definitive analytic methods are available and are properly employed. Inclusion (could have originated from) and attribution (did originate from) require increasingly informative methods and samples with sufficiently exploitable and informative properties. More than one method, each targeting different constituents, is often used in analytic and comparative processes, with the results complied to arrive at a final determination. Having a statistical basis for the analysis and comparison strengthens the value and weight of the results and confidence in the interpretation.

Figure 31.1 The Forensic Continuum



If physical evidence is available, forensic sciences can be used to help formulate leads, gather intelligence and conduct analyses to help inform legal and policy decision processes.

Today, once the event or person of interest has been identified, putative forensic evidence is collected and exploited for lead information during the early stages of an investigation, with the most reliable and credible evidence used to build and shape the investigation and prosecution (see Figure 31.2). The results of forensic analyses are only as good as their accuracy and reliability in the context of the matter at hand.

Figure 31.2 Forensic science use

MICROBIAL FORENSICS

Microbial forensics is a specialized forensic discipline which focuses on microbes, toxins and associated materials and equipment as physical evidence to derive information of value for the investigative process. It is one of the more recent forensic disciplines, and emerged around 15 years ago out of the US Federal Bureau of Investigation (FBI) forensic laboratory when the FBI created the US national forensic investigative programmes for weapons of mass destruction. Microbial forensics was created to investigate and prevent individuals seeking to acquire, develop or use biological weapons for malicious purposes. Substantial investment in microbial forensics in the United States followed as a result of investigations in the anthrax letters of 2001. Microbial forensics uses a number of scientific disciplines such as bacteriology and virology, population genetics and biostatistics, analytical chemistry and biochemistry, and veterinary and plant pathology. Whilst various US agencies have priority lists, the United States Centers for Disease Control and Prevention priority threat agents serve as a useful guide against which to build effective microbial forensic capabilities.

In the United States, where the most developed capability presently exists, microbial forensics experts from the government, national laboratories, academia and industry continue to develop increasingly diverse and exploitative methods and protocols. They also collaborate with experts from classical (or traditional) forensic disciplines to develop and validate

collection, processing and analytic methods. Other states have recently shown interest in developing their own microbial forensic capabilities.

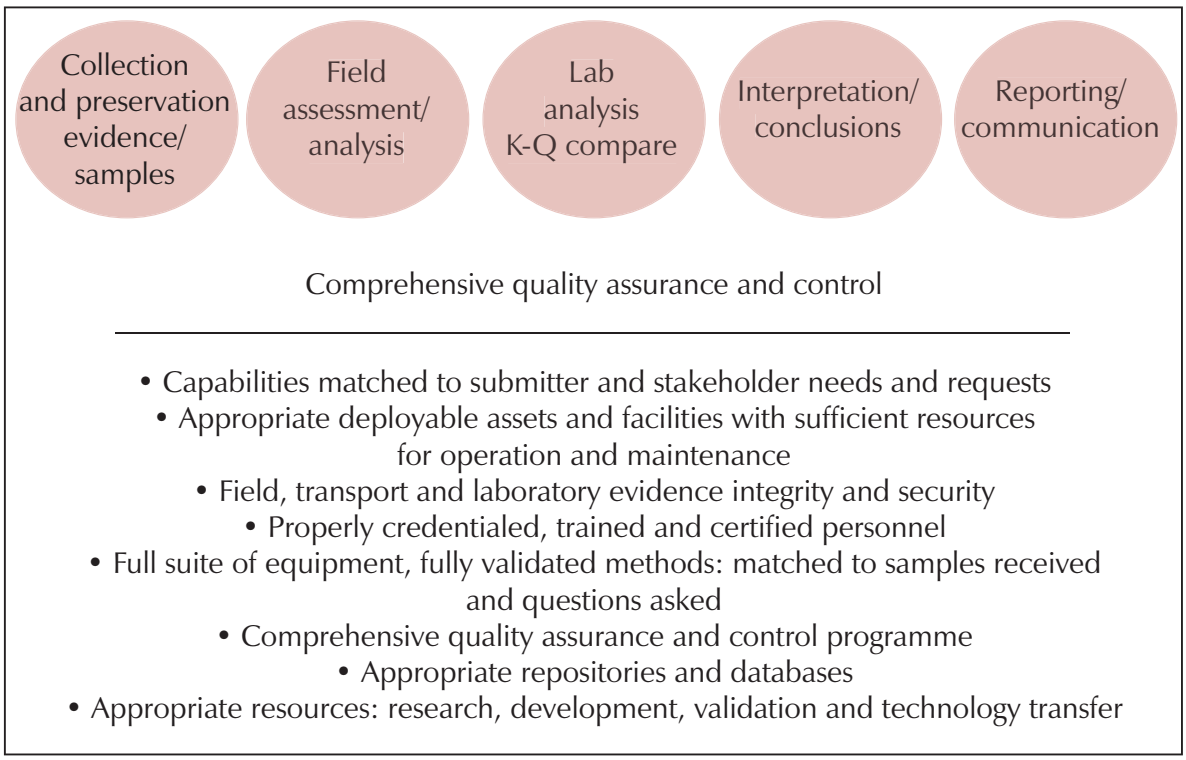
INTERNATIONALIZING MICROBIAL FORENSICS COULD ADVANCE GLOBAL BIOSECURITY

Global biosecurity would be strengthened by the establishment of a robust, internationally-sanctioned microbial forensics regime, similar to the one which exists for chemical and nuclear weapons non-proliferation. If a competent and independent field and laboratory capability could be established and available to support all UN-directed investigations, legal and policy actions could be strengthened, and perpetrators, potential perpetrators and enablers would be held accountable.

Whilst the United States currently has the most competent capability and experience, a course chartered under UN auspices could be pursued though international collaboration to establish an effective framework that would meet the highest expectations to support international law- and policy-driven actions. Accuracy, reliability and defensibility would be the performance pillars of the envisioned end-to-end system.

An ideal forensic system with its standard components is depicted in Figure 31.3. “K-Q Compare” is the requirement for side-by-side comparisons of known (reference) samples and evidentiary samples which should be conducted using consistent and validated methods whenever source determinations are being attempted. A robust, continually improving system is supported and strengthened by validated requirements, incorporating the expectations of users, sufficient resources and built-in performance standards and accountability, as listed below Figure 31.3.

Figure 31.3 An ideal forensic system



The commitment is made to establish the fullest capability possible within known limits of science and practice, and that the budgetary resources are obligated to establish and sustain the system from end-to-end. The system must be able to:

- adapt to the advancement of science and technology;
- respond to validated requirements and stakeholder expectations;
- address needs and gaps to provide for full forensic analysis of current and emerging biological threats;
- address new requirements for system quality and timeliness; and
- respond to fluxes in requests for analysis and reporting.

As a new forensic discipline, microbial forensics has many recognized scientific gaps and operational constraints as well. Knowledge and capability must be advanced through aggressive, leveraged research, training and exercise programmes. Standardized, fully validated collection, analysis and reporting methods should be established for all priority pathogens. New threats and emerging technologies should also be

prepared for to help minimize surprise. Users and stakeholders should also be trained and exercised to understand and use the microbial forensics system to its full capacity and capability, whether from the investigative or decision-making perspectives. Policy and legal requirements should be established together and validated and updated on an intermittent basis to maintain responsiveness and value.

THE PATH FORWARD

The international community should soon begin the process of assessing a formalized role for microbial forensics to support investigations and determinations of attribution. In this regard, a series of international meetings attended by appropriate scientific, legal and policy experts should be convened to address the following questions:

1. Can there or should there be universal acceptance of an international forensic capability for biological threat agents and associated classical forensic evidence under UN authority?
2. Is there a formalized role for microbial forensics and classical forensics under the authority of the United Nations and pertinent agreements?
3. If there is a role:

    - What is required to warrant and justify establishing, gaining acceptance and employing such a capability?
    - How should it be defined and organized?
    - Who should provide leadership and oversight?
    - How should it be resourced?
    - What is the process that should be undertaken to achieve, maintain and sustain the expected capability for best value?
    - How would science, investigation, law and policy interface and leverage each other for the desired performance?
    - How would independence, objectivity and confidence in the capability be established and sustained?
    - How could it fit with other, related international and national forensic capabilities?

4. If it is determined that microbial forensics can and should be established under UN authority, the following steps should be considered:

   - issue the appropriate communication supporting the establishment of an international microbial forensics capability and assign leadership;
   - develop the authorities and mechanisms to establish priorities, identify and validate requirements, define desired attributes and performance characteristics of the forensic capability;
   - develop and validate frameworks for international law and policy to use and test the results and interpretations from microbial forensic analyses in international legal and policy decisions;
   - establish and gain acceptance for the above;
   - identify collaborative pilot or demonstration efforts through which the desired microbial forensic capability can be initialized; and
   - from these pilot efforts, develop and validate an overall strategy with ordered priorities, and then a plan with objectives, effective progress measures and a sufficient budget, with options to fully establish the agreed-to capability.

CONCLUSION

A robust, credible and fully resourced microbial forensic investigative capability, augmented with classic forensic resources, could add significant value and impact to UN-led investigations and inspections regarding suspected and actual biological weapons development, possession and use. It would also hold proliferators and their enablers accountable and potentially contribute to deterrence. The international community should begin a series of discussions on several levels with the goal of establishing such a capability. Science, law and policy should be integrated when considering such an enterprise, which could operate under the Secretary General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons.

SECTION E

CONCLUSIONS

CHAPTER 32

BUILDING ON SUCCESS: THE FUTURE OF THE INTERSESSIONAL PROCESS

Richard Lennane

If you have read this far, you cannot fail to have been struck by the extraordinary breadth and depth of the information presented. Effectively implementing the Biological Weapons Convention (BWC) is a complex and multidimensional challenge, involving many actors working in a broad array of related and disparate fields, in government and beyond. If the Intersessional Process has done nothing else, it has shown that there is a great deal more to national implementation than the concise terms of Article IV of the BWC would suggest. Nobody can claim to be an expert in BWC implementation: effective implementation must derive from the coordinated efforts of many different experts.

Looking back to the start of the first Intersessional Process, in 2003, it is barely conceivable that such an apparently limited set of meetings—a bare-bones "rescue package" assembled from the wreckage of the Fifth Review Conference—could have had such success in promoting and facilitating effective national implementation of the convention on a practical level. Expectations for the first Intersessional Process were very low: it was only grudgingly agreed as being better than no action at all, and widely derided as a time-filling talking shop of little practical consequence. As we have seen, these low expectations and dismissive criticisms were fundamentally misguided—as most of the critics (including me) have been only too happy to admit.

With the 2007–2010 Intersessional Process complete, one of the key tasks for the Seventh Review Conference, in December 2011, will be to decide what to do next. Should there be a third Intersessional Process, running along the same lines from 2012–2015? Or is it time to alter the approach and try some new ideas? If the latter, what are the essential elements to preserve from the Intersessional Process, and what are some

of the shortcomings or gaps that might be filled? This final chapter will examine these questions, and look at some options for future mechanisms to support effective national implementation.

HAS THE INTERSESSIONAL PROCESS RUN ITS COURSE?

Given the success of the 2003–2005 and 2007–2010 Intersessional Processes, one might ask why anyone would suggest that the Seventh Review Conference should not just commission a third such process. The major concern is that the process risks becoming repetitive, and thus less interesting and effective. Each of the two previous processes operated the same way: one or two dedicated topics were considered each year, and the overall cycle of topics for each of the processes—differences of wording and emphasis aside—was quite similar. There is thus a feeling among some states parties that going around the same cycle of discussions again would add little more, at least for those states which participated in the previous processes. There would be more and more repetition, and less fresh material to keep participants interested, stimulated and engaged.

The counter-argument is that the topics remain important and relevant, that many aspects of them remain to be fully discussed and explored, and that even if there is a degree of repetition, there is a constant turnover of officials and experts who would benefit nevertheless.

Both arguments are valid; it is therefore probably best to find a course of action that preserves the important benefits of the Intersessional Process, while also refreshing and restructuring the programme in order to boost interest and attract new participants.

PRESERVING THE KEY ELEMENTS

Reading over the previous chapters, there are a number of qualities and factors that clearly emerge as having been fundamental to the success of the Intersessional Process:

- Broad participation: a wide range of national experts and officials from different agencies (foreign affairs, defence, health, agriculture and law-enforcement, among others), as well as experts from

intergovernmental organizations, scientific and professional bodies, industry and academia.

- Opportunities for interaction and sharing information: from formal presentations, to discussion panels, poster sessions, lunchtime seminars, and informal interactions in the corridors and over coffee.
- Relevant and well-defined topics: the topics drove the interest and participation, helped identify relevant participants outside national governments and focused discussion.

There are also some factors that perhaps played a significant role, but are more difficult to assess:

- No mandate for taking decisions: it is likely, although difficult to prove, that because it was widely understood that the Intersessional Process would not negotiate or agree binding decisions, the participating states parties were more relaxed, flexible and open-minded, and the discussion was freer, less politically-charged, and more collaborative and focused on practical issues.
- Recording of ideas and "common understandings": the method developed in 2004 of compiling and annexing to the report all the "considerations, lessons, perspectives, recommendations, conclusions and proposals" put forward by anyone at the Meeting of Experts, in their raw form with minimal editing, probably helped by ensuring that everyone felt included and that there was no need for negotiation over what should be included or how it should be expressed. The subsequent distillation of these ideas by the Chairman into a "synthesis paper", under his own responsibility, provided focus and coherence while still avoiding the need for negotiation. The final step of developing the "common understandings" in the report of the Meeting of States Parties, which did involve negotiation, was by that stage relatively painless, being built on a sound and inclusive foundation.

In designing a new Intersessional Process, it would therefore make sense to try to retain as many of these elements as possible. The one element that may need some more reflection is the question of a mandate for taking decisions. Indeed, there have already been suggestions from some states parties that a future Intersessional Process should be empowered to take certain decisions, rather than having to leave everything to the next five-yearly Review Conference. There is certainly something to be said for

this, especially in cases where the Intersessional Process has been given some specific task—revising the confidence-building measures (CBMs), for example—where immediate adoption and implementation of the results would be natural and desirable. But we should perhaps be cautious about bestowing an open-ended decision-making mandate, as this may tend to prompt political caution, dampen the expert discussion, and risk altering or losing altogether the essential spirit of the Intersessional Process.

ADDRESSING THE SHORTCOMINGS

Just as there are elements we should work to retain, there are a number of areas where the Intersessional Process has been criticized, or at least could be said to have room for improvement:

- Intermittent focus: each topic (or pair of topics) was considered intensively and in depth in a particular year—and then ignored. There was no follow-up or development; ideas and proposals were left hanging; and while many individual governments or individual experts may have taken action based on the information shared, there was no coordinated effort to do anything with it.
- Some issues were not included: the topics covered by the Intersessional Processes were all highly relevant and appropriate, but there were other possibly relevant and appropriate topics that were not included at all or only peripherally. There was also no mechanism to add or alter topics in response to current developments (as it happened, this did not turn out to be a serious shortcoming in either of the Intersessional Processes to date, but it is easy to imagine it could be a problem in future).
- Too much depended on a single chairman: the Chairman of each year of the Intersessional Process bore essentially the sole responsibility for the year's work, preparing for the meetings, identifying relevant organizations and experts, steering the discussions, chairing the meetings, and shaping the outcome—as well as acting as a global ambassador for the BWC, attending workshops and seminars around the world, and lobbying for universality. The Implementation Support Unit (ISU) provided practical assistance, but it was still a heavy load, and often required difficult choices about what could and could not be done.

- Lack of structured activity between meetings: although there was often a lot of ad hoc activity, visits, consultations and workshops in the lead-up to the Meeting of Experts and between the Meeting of Experts and the Meeting of States Parties, there was little if any structure or planning involved in this. This resulted in uneven involvement of different states, regions and organizations, and probably missed opportunities to inform, develop and fully exploit the potential benefits of the meetings.
- The Meeting of States Parties was under-utilized: there was not enough to fill the five scheduled days of formal meeting time. There were typically a few extra presentations that were updates or "leftovers" from the Meeting of Experts, some generally brief and superficial discussion of the Chairman's synthesis paper, and one session devoted to the ISU and universalization reports. The rest of the time was spent by the Chairman in bilateral and small-group consultations, developing (dare we say negotiating?) the substantive paragraphs for the report. Although the results were good, it is questionable whether five expensive days of formal meeting time were required to achieve them.
- Participation was limited by financial constraints: the great benefit of the Intersessional Process, and the Meeting of Experts in particular, was the opportunity for experts and officials to interact in person, to discuss common interests and problems, and exchange ideas and experience. Even if the meetings had produced no reports at all, they would still have been useful just for the function of bringing relevant actors together. Unfortunately, because of lack of funds, many developing states were unable to send experts to Geneva. Although a few states parties contributed to some ad hoc sponsorship arrangements, the lack of a structured sponsorship programme did detract from the overall utility of the Intersessional Process.

This is not an exhaustive list, and naturally opinions will vary as to the relative importance of the various elements. Although I counted the lack of a decision-making mandate as an advantage for the process, some might reasonably argue that it was also a shortcoming—although in looking over the reports of the 2007–2010 Intersessional Process, there are not many things which immediately present themselves as decisions that could and should have been taken.

DESIGNING A NEW PROCESS

Having identified the elements of the old process we want to retain, and looked at the aspects we want to correct or improve, how might we incorporate these into a new Intersessional Process? There are many approaches that could be considered. I will describe one possibility.

The basic pattern of holding two meetings a year—a technically-oriented meeting for experts mid-year, and a more policy-oriented meeting at the end of the year—would be retained. But the process would be restructured into three open-ended working groups (or standing committees, or some other title—I will use working groups), each with a general area of responsibility within the overall range of BWC issues, as follows:

Working group 1: implementation and compliance
Working group 2: science, technology and outreach
Working group 3: cooperation, assistance and capacity-building

Table 32.1 Possible outline of working groups

WG1: implementation and compliance	**WG2: science, technology and outreach**
National implementation (policy aspects) Biosecurity Export controls Information exchange (CBMs or replacement) Response to alleged use/violations Other compliance measures	Scientific/technological developments relevant to the convention Oversight of science Education and awareness-raising Codes of conduct Liaison with the scientific community, professional bodies and industry
WG3: cooperation, assistance and capacity-building	
Coordination of assistance activities and Article X implementation Capacity-building for national implementation, biosafety/biosecurity, disease surveillance, etc. Liaison with FAO/OIE WHO, etc. Sponsorship programme Universalization	

Each working group would have a coordinator, appointed annually, and there would also be an overall BWC chair (as is the case now). The working groups would meet formally for one week of technical discussions mid-year (with each group perhaps meeting for one to one-and-a-half days), and more briefly again in November/December as part of the annual Meeting of States Parties.

The general mandate of the working groups would be to monitor and assess progress and activity in each topic area, and to encourage and coordinate further work. The respective coordinators would be expected not just to chair the actual meetings of the working groups, but to encourage and coordinate relevant activity—whether national, regional or international—throughout the year. Each working group would set its own detailed agenda within its overall area of responsibility, allowing the flexibility to consider and follow-up on some issues every year, and others only intermittently as required. Perhaps some topics could be mandated in advance by the Review Conference to avoid wasting too much time on discussions of when to consider what. There could also be utility in still setting an annual special topic for extra attention at the Meeting of Experts each year, outside the working group structure. But in general, the working groups would manage their areas of responsibility, and interact with the relevant organizations, experts and other stakeholders, according to the interests of the states parties and the coordinator.

For example, the working group on implementation and compliance would meet to review progress and share best practices on national implementing legislation, export control and biosecurity measures, to consider CBM submissions and oversee the process, and to develop or fine-tune international procedures for responding to alleged use. Before and after the meetings, the coordinator of the group would work with the ISU (or successor), interested states parties and relevant organizations to organize workshops and seminars, develop proposals and resources, and generally "promote effective action" on implementation.

The annual Meeting of States Parties would draw together the work of the three working groups, issue endorsements or recommendations where consensus can be found, and provide a forum for addressing broader cross-cutting issues or deciding a collective response to particular developments (such as withdrawal of a state party from the convention and questions over whether a new technology is covered by Article I, among

others). The duration of the Meeting of States Parties could probably be reduced to three days: one day for brief reporting meetings of the three working groups, one day for consideration of any cross-cutting or general convention issues, and one day for preparing and adopting the report.
The three coordinators of the working groups and the Chair of the Meeting of States Parties, perhaps together with the three regional group coordinators and the three Depositaries, would form a kind of management committee for the convention. This could be formally constituted as such or left as an informal working arrangement—but in either case it would have the effect of spreading more widely the responsibility for managing the Intersessional Process and the overall implementation of the convention.

Finally, a sponsorship programme would be established to facilitate broader participation in the process by experts from developing states, with states parties and perhaps other organizations invited to make voluntary contributions. The programme could be overseen by working group 3, or by the management committee, and would be administered by the ISU.

CONCLUSION: THE WAY FORWARD

The proposal set out above is just one way of incorporating the desired qualities into a new Intersessional Process. There may be other approaches that are equally appropriate, or even better. There is also the question, which I have deliberately skirted in my proposal, of the decision-making mandate. But whatever states parties choose to do at the Seventh Review Conference, it is to be hoped that it facilitates and nurtures more of the kinds of innovation, imagination, dedication, applied knowledge and expertise collected in this book. If it does, the new process will make a genuine and significant contribution to reducing the risks posed to global security by biological weapons, and to ensuring that biological science and technology are safely and securely developed for the benefit of all.

ANNEX
A SUMMARY OF THE COMMON UNDERSTANDINGS IDENTIFIED DURING THE 2007–2010 INTERSESSIONAL PROCESS

National implementation

Table 1 Common understandings on national implementation reached at the 2007 Meeting of States Parties

Components	Mechanisms
Sufficient penal legislation for prosecuting prohibited activities Prohibition of assisting, encouraging or inducing others to conduct prohibited activities Strengthening national capacity (including human and technological resources) Effective export and import controls Avoid hampering peaceful use of biological sciences	Promoting cooperation and coordination among government agencies Defining roles of different agencies and bodies Raising awareness of BTWC among relevant stakeholders Improving dialogue and communication among relevant stakeholders Establishing a central body or lead organization Creating a national implementation action plan
Enforcement capacity	**Ongoing activities**
Building capacity to collect evidence Developing early warning systems Enhancing coordination between relevant agencies Training law enforcement personnel Providing enforcement agencies with necessary scientific and technological support	Regular reviews of adopted measures Ensuring continued relevance of national measures in light of scientific and technological development Updating lists of agents and equipment Implementing additional measures as required

Notes: Table 1 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the 2007 Meeting of States Parties*, document BWC/MSP/2007/5, 7 January 2008, paragraphs 19–26.

Regional and subregional cooperation

Table 2 Common understandings on regional and sub-regional cooperation reached at the 2007 BTWC Meeting of States Parties

Approaches	Provision of resources
Develop common approaches to implementation Provide relevant assistance and support Building upon shared languages and legal traditions Engage pre-existing regional resources Include implementation of BTWC on agenda of regional meetings and activities	States parties in a position to do so should provide technical assistance and support to requesting states parties Use Implementation Support Unit (ISU) as a clearing house Make full use of resources and expertise in other states parties and in international and regional organizations
Information sharing	
Nominate a national point of contact Inform ISU of national measures and any updates or changes to them Inform ISU of any relevant regional or sub-regional activities	

Notes: Table 2 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the 2007 Meeting of States Parties*, document BWC/MSP/2007/5, 7 January 2008, paragraphs 19–26.

Table 3 Common understandings on biosafety and biosecurity reached at the 2008 Meeting of States Parties

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

Notes: Table 3 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008, paragraphs 19–28.

Oversight, education, awareness-raising and codes of conduct

Table 4 Common understandings on oversight, education, awareness-raising and codes of conduct reached at the 2008 Meeting of States Parties

Oversight characteristics	Education and awareness-raising components
Develop national oversight frameworks: – to prevent agents and toxins being used as weapons – to oversee relevant people, materials, knowledge and information – to oversee the entire scientific life cycle – to cover private and public sectors: – that are proportional to risk – that avoid unnecessary burdens – that are practical and usable – that do not unduly restrict permitted activities – with the involvement of stakeholders in all stages of design and implementation – that can be harmonized regionally and internationally	Formal requirements for seminars, modules or courses in relevant scientific education and training programmes and continuing professional education that: – explain the risks associated with the malign use of biology – cover moral and ethical obligations – provide guidance on the types of activities which could be prohibited – are supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications and audio-visual materials – address leading scientists and managers as well as future generations of scientists – can be integrated into existing national, regional and international efforts
Next steps for codes of conduct	
Complement national legislative, regulatory and oversight frameworks Help guide science so it is not used for prohibited purposes Further develop strategies to encourage voluntary adoption of codes	

Notes: Table 4 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008, paragraphs 19–28.

Dealing with disease

Table 5 Common understandings on pillars for building capacity to deal with disease, as reached at the 2009 Meeting of States Parties

Infrastructure components	Developing human resources
Disease surveillance systems which continuously collect and analyse data from multiple sources Capacity for rapid detection and identification of pathogens Primary health-care, veterinary and phytosanitary services Emergency and epidemiological response capabilities Communications capabilities Appropriate national regulatory framework to provide command structure and necessary resources Treatment capabilities, including diagnostics, vaccines and medicines	Make use of national, regional and international workshops Ensure training materials are available in local languages Take advantage of both computer-based and hands-on training Foster a more interdisciplinary approach to dealing with disease Engage all relevant sectors Identify ways to reduce "brain-drain" Need for political leadership Provide sponsorship for training, exchange visits and travel to the Meetings of Experts
Implementing shared practices	
Use standard operating procedures to enhance sustainability, improve trust, build confidence, contribute to quality control and foster the highest standards of professional performance Develop and use best practice for surveillance, management, laboratory practice, manufacturing, safety, security, diagnostics and trade Work with all relevant ministries to develop legislation, standards and guidelines Strengthen international protocols for the rapid sharing of information Make use of existing case studies to improve existing practices and procedures	

Notes: Table 5 summarizes the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009, paragraphs 23–31.

Table 6 Common understandings on cross-cutting themes for building capacity to deal with disease, as reached at the 2009 Meeting of States Parties

Sustainability	Improving integration
Pool resources Make funding processes longer-term and more predictable Ensure ownership by the receiving country Address needs for day-to-day maintenance Tailor activities to meet differing circumstances of each recipient state Take full advantage of existing resources Utilize twinning programmes Use collaborative projects	Ensure effective communication and coordination among human, animal and plant health sectors Use an inter-disciplinary, all-hazards approach Improve how government departments and agencies work with the private sector, academia and non-governmental experts Make use of public-private partnerships
Enhancing coordination	**Overcoming challenges**
Take advantage of all appropriate routes for assistance—bilateral, regional, international and multilateral Forge North-South, South-South and North-North partnerships Improve coordination and information sharing among: – assistance providers – states parties and international efforts to tackle disease – national institutions, departments, agencies and other stakeholders	Mobilize resources, including financial resources, to facilitate the widest possible exchange of equipment, material and scientific and technological information States parties seeking to build capacity should identify specific needs and requirements and seek partnership States parties in a position to do so should provide assistance and support Make use of the ISU to facilitate communication and partnerships, and act as a clearing-house for information and sources of cooperation

Notes: Table 6 summarizes the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009, paragraphs 23–31.

Responding to the use of a biological weapon

Table 7 Common understandings on responding to an alleged use of a biological weapon, as reached at the 2010 Meeting of States Parties

Approaches	Health components
Effective cooperation and sustainable partnerships Ensuring efficiency irrespective of the cause of an outbreak Covering diseases and toxins that harm humans, animals, plants or the environment Putting capabilities in place before they are required Making use of appropriate experts and laboratories Taking into account developments in science and technology	Access to: – a relevant diagnostic capacity – sampling and epidemiology tools – diagnostic and detection techniques, tools and equipment – adequate technical expertise – international, regional and national laboratory networks – standards, standard operating procedures and best practices – research and development of vaccines and diagnostic reagents
Security components	**Building capacity**
A coordinated government approach in emergency management Addressing the full range of possible implications Establishing clear channels of communication and command Mechanisms for accessing expert advice Regular training and exercises A comprehensive communication strategy Cross-sector coordination Sufficient financing	Working together to: – ensure access to the necessary components – promote and facilitate the generation, transfer and acquisition of new knowledge and technologies – strengthen human resources – identify opportunities for collaborative research and sharing advances in science and technology – share biorisk standards and best practices

Notes: Table 7 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2010/6, 17 December 2010, paragraphs 19–30.

Table 8 Common understandings on roles of various actors when responding to an alleged use of a biological weapon, as reached at the 2010 BTWC Meeting of States Parties

Role of the convention	Role of states parties
The convention is an appropriate and capable instrument for: – bilateral, regional or multilateral consultations for the provision of assistance – developing clearer and more detailed procedures for submitting requests for assistance – developing clearer and more detailed procedures for providing assistance – developing a dataset on sources of assistance – developing a mechanism to request assistance	Providing timely emergency assistance pending a decision by the UN Security Council Ensuring relevant efforts are in accordance with national laws and regulations Working to build their national capacities according to their specific needs and circumstances Working to improve effective cooperation between the health and security sectors by: – fostering mutual awareness – improving information exchange – undertaking joint training activities
Role of international parties	**Outstanding challenges**
Encouraging relevant organizations to: – work together more closely – address specific relevant aspects of the threats posed by alleged use – assist states parties to build their national capacities	A need for clear procedures for submitting requests for assistance A need for clear procedures for responding to a case of alleged use A need for additional resources in the human and animal health fields, and especially for plant health Overcoming the sensitivities of working at the interface between public health and security Fully addressing the public health and humanitarian imperatives of a prompt and timely response

Notes: Table 8 summarizes Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2010/6, 17 December 2010, paragraphs 19-30.

Notes

Chapter 1
Introduction

1 The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction opened for signature on 10 April 1972 and entered into force on 26 March 1975.
2 Statement by Secretary-General Kofi Annan to the Sixth Review Conference of the BWC, Geneva, 20 November 2006.
3 Statement by Ambassador Jayant Prasad of India to the Sixth Review Conference of the BWC, Geneva, 20 November 2006.
4 Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.II/13/II, 30 September 1986, p. 4.
5 Ibid., p. 4.

Chapter 3
National implementation through an effective legislative framework

1 Security Council, *Resolution 1540*, UN document S/RES/1540 (2004), 28 April 2004.
2 Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006, p. 10.
3 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the 2007 Meeting of States Parties*, document BWC/MSP/2007/5, 7 January 2008, p. 5.
4 Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006, p. 11.

Chapter 4
The work of the BWC in 2007

1 This chapter is adapted from text developed by the ISU for the *United Nations Disarmament Yearbook: 2007*, UNODA, 2008. For information on

earlier meetings see the yearbooks for 2003 through 2006. Full texts of the *United Nations Disarmament Yearbook* can be found online at <www.un.org/disarmament/HomePage/ODAPublications/Yearbook/index.shtml>.

2 The African Union Commission, the International Committee of the Red Cross, the International Criminal Police Organization (INTERPOL), the League of Arab States, and the Organization for the Prohibition of Chemical Weapons (OPCW).

3 UNODA and the United Nations Institute for Disarmament Research.

4 All statements, documents and presentations made during the meetings can be found on the BWC website at <www.unog.ch/bwc>.

5 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2007/MX/3, 3 September 2007.

6 Closing remarks of the Chairman, Ambassador Masood Khan of Pakistan, at the Meeting of Experts 2007, 24 August 2007.

7 See Annex 1 of Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the 2007 Meeting of States Parties*, document BWC/MSP/2007/5, 7 January 2008, pp. 8–14.

8 Closing remarks of the Chairman, Ambassador Masood Kahn of Pakistan, at the Meeting of States Parties 2007, 14 December 2007.

9 See ISU, *Additional Understandings and Agreements Reached by Review Conferences Relating to each Article of the Biological Weapons Convention*, 2007.

Chapter 5
The work of the BWC in 2008

1 This chapter is adapted from text developed by the ISU for the *United Nations Disarmament Yearbook: 2008*, UNODA, 2009. Full texts of the *United Nations Disarmament Yearbook* can be found online at <www.un.org/disarmament/HomePage/ODAPublications/Yearbook/index.shtml>.

2 United Nations Office for Disarmament Affairs (UNODA), United Nations Institute for Disarmament Research (UNIDIR), the United Nations Environment Programme and the 1540 Committee.

3 The European Commission (EC), the International Centre for Genetic Engineering and Biotechnology, the International Committee of the Red Cross, the Organisation for Economic Co-operation and Development, the United Nations Educational, Scientific and Cultural Organization, the World Health Organization (WHO) and the World Organisation for Animal Health (OIE).

4 The American Biological Safety Association, the Asia–Pacific Biosafety Association, AstraZeneca, the European Biosafety Association, GlaxoSmithKline, the InterAcademy Panel on International Issues (IAP), the International Biosafety Working Group (IBWG), the International Council for the Life Sciences, the International Network of Engineers and Scientists for Global Responsibility, the International Union of Biochemistry and Molecular Biology, the International Union of Pure and Applied Chemistry, the J. Craig Venter Institute, and the National Academy of Sciences (NAS).

5 All statements, documents and presentations made during the meetings can be found on the BWC website at <http://www.unog.ch/bwc>.

6 For further information see the *United Nations Disarmament Year Book: 2007*, UNODA, 2008.

7 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2008/MX/3, 8 September 2008.

8 Closing remarks of the Chairman at the Meeting of Experts on 22 August 2008.

9 UNODA and UNIDIR.

10 The ICRC, INTERPOL, the OIE and the WHO. The EC also participated.

11 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Chairman on universalization activities*, document BWC/MSP/2008/4, 28 November 2008.

12 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *2008 Report of the Implementation Support Unit*, document BWC/MSP/2008/3, 28 November 2008.

13 Closing remarks of the Chairman at the Meeting of States Parties on 5 December 2008.

14 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008.

15 See Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Background information document showing the additional understandings and agreements reached by the Review Conferences relating to each Article of the convention*, document BWC/CONF.V1/INF.1, 11 July 2006.

16 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008, pp. 4–5.

17 Ibid., p. 7.

Chapter 6
The work of the BWC in 2009

1 This chapter is adapted from text developed by the ISU for the *United Nations Disarmament Yearbook: 2009*, UNODA, 2010. Full texts of the *United Nations Disarmament Yearbook* can be found online at <www.un.org/disarmament/HomePage/ODAPublications/Yearbook/index.shtml>.

2 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2009/MX/3, 16 October 2009, p. 2.

3 United Nations Office for Disarmament Affairs (UNODA), the United Nations Institute for Disarmament Research (UNIDIR) and the United Nations Interregional Crime and Justice Research Institute (UNICRI).

4 The European Centre for Disease Prevention and Control (ECDC), the European Commission (EC), the Food and Agriculture Organization of the United Nations, the International Committee of the Red Cross (ICRC), the International Science and Technology Centre, the World Health Organization (WHO) and the World Organisation for Animal Health.

5 Amyris Biotechnologies, the Biosafety and Biosecurity International Conference Series, the European Biosafety Association, HealthMap, the International Council for the Life Sciences (ICLS), the International Security and Biopolicy Institute (ISBI), the International Vaccine Institute, the National Center for Security and Crisis Management (Jordan), the Nuclear Threat Initiative Global Health Security Initiative and ProMED-mail.

6 All statements, documents and presentations made during the Meeting of Experts can be found on the BWC website at <www.unog.ch/bwc>.

7 The ISU submitted the following papers to the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: *Recent developments in intergovernmental organizations relevant to disease surveillance, detection, diagnosis and containment*; *Recent international, regional and non-governmental developments relevant to disease surveillance, detection, diagnosis and containment*, document BWC/MSP/2009/MX/INF.2, 24 July 2009; *Previous agreements and understandings under the convention relevant to capacity building in the fields of disease surveillance, detection, diagnosis and containment*, document BWC/MSP/2009/MX/INF.3, 24 July 2009; *Provision of assistance and capacity building in other international settings*, document BWC/MSP/2009/MX/INF.4, 29 July 2009; and *Provisional contact details for organizations building capacity in the fields*

disease surveillance, detection, diagnosis and containment, document BWC/MSP/2009/MX/INF.5, 26 August 2009.

8 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2009/MX/3, 16 October 2009.

9 Chairman's closing remarks at the BWC Meeting of Experts 2009.

10 UNODA, UNIDIR and UNICRI.

11 The European Union, the ICRC, the Organization for the Prohibition of Chemical Weapons and the WHO.

12 Opening statements and presentations made during the meetings can be found on the BWC website <http://www.unog.ch/bwc>.

13 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009.

Chapter 7
The work of the BWC in 2010

1 This chapter is adapted from text developed by the ISU for the *United Nations Disarmament Yearbook: 2010*, UNODA, 2011. Full texts of the *United Nations Disarmament Yearbook* can be found online at <www.un.org/disarmament/HomePage/ODAPublications/Yearbook/index.shtml>.

2 Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006, p. 21.

3 United Nations Office for Disarmament Affairs (UNODA) and the United Nations Interregional Crime and Justice Research Institute (UNICRI).

4 The European Union, the Food and Agriculture Organization of the United Nations, the International Committee of the Red Cross (ICRC), the International Criminal Police Organization (INTERPOL), the Organisation for Economic Co-operation and Development, the Organization for the Prohibition of Chemical Weapons (OPCW), the World Health Organization (WHO) and the World Organisation for Animal Health (OIE).

5 The Virginia Polytechnic Institute and State University and the University of the Philippines College of Medicine.

6 All statements, documents and presentations made during the meetings can be found on the BWC website at <www.unog.ch/bwc>.

7 The ISU submitted the following papers to the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their

Destruction: *Previous agreements and understandings under the convention relevant to the provision of assistance and coordination in the case of alleged use of biological or toxin weapons*, document BWC/MSP/2010/MX/INF.1, 14 June 2010; *The role of international organizations in the provision of assistance and coordination in the case of alleged use of biological or toxin weapons*, document BWC/MSP/2010/MX/INF.2, 5 August 2010; and *Technical guidance for preparing for and responding to alleged use of biological or toxin weapons*, document BWC/MSP/2010/MX/INF.3, 5 August 2010.

8 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2010/MX/3, 8 September 2010.

9 Reported by the ISU, "Biological Weapons Convention Expert Meeting Concludes", 27 August 2010.

10 UNODA and UNICRI.

11 The European Union, the ICRC, INTERPOL, the OIE, the OPCW, and the WHO.

12 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Chairman on universalization activities*, document BWC/MSP/2010/4, 30 November 2010.

13 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *2010 Report of the Implementation Support Unit*, document BWC/MSP/2010/2, 30 November 2010.

14 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2010/6, 17 December 2010.

15 Reported by the ISU, "Biological Weapons Convention Meeting of States Parties Concludes in Geneva", 10 December 2010.

Chapter 8
Building a regime to secure biology in the twenty-first century

1 This chapter draws heavily on P. Millett, "The Biological Weapons Convention: Securing Biology in the Twenty-first Century", *Journal of Conflict and Security Law*, vol. 15, no. 1, 2010, pp. 25–43.

2 P. Millett, "Why the 2011 BTWC RevCon Might Not Be Business as Usual", *Disarmament Forum*, No. 1, UNIDIR, 2011, pp. 3–12.

3 For example see M. ElBaradei, "Introductory Statement to the Board of Governors", International Atomic Energy Agency, Vienna, 2 March 2009.

4 In order to improve civil society involvement in the Chemical Weapons Convention, the Chemical Weapons Convention Coalition was launched in December 2009. For example see the entry for 4 December 2009 in the VERTIC News Archive 2009.

5 For further information see the chapter "Biological and Chemical Weapons", in *United Nations Disarmament Yearbook: 2009*, vol. 34, part II, UNODA, 2010, pp. 57–82. A full list of the series can be found at <www.un.org/disarmament/HomePage/ODAPublications/Yearbook/>.

6 For an example of the mandate of the current Intersessional Process, see Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006.

Chapter 9
Introducing biosafety and biosecurity

1 This chapter is adapted from "Bring Biologists on Board: Looking Back on the Work of the Biological Weapons Convention in 2008", Statement by Ambassador Georgi Avramchev delivered at the Workshop on Biosecurity, Beijing, 7–9 December 2008.

2 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2008/MX3, 8 September 2008, p. 1.

Chapter 10
A summary of the panel discussion on risk governance

1 A full transcript of the panel discussion and opening remarks made by the Chairman are available at <www.unog.ch/bwc>.

2 Fifty-Fifth World Health Assembly, *Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health*, document WHA55.16, 18 May 2002.

Chapter 11
Biosafety and biosecurity concepts and approaches

1 See "WHA58.29: Enhancement of laboratory biosafety", in Fifty-Eighth World Health Assembly, *Resolutions*, WHO, p. 124.

2 The terms "biosafety" and "biosecurity" have different meanings in different settings. For more information see Meeting of the States Parties to

the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Biosafety and biosecurity*, document BWC/MSP/2008/MX/INF.1, 24 June 2008.

3 WHO, *Laboratory Biosafety Manual: Third Edition*, 2004, p. 47.

4 WHO, *Biorisk Management: Laboratory Biosecurity Guidance*, 2006, p. iv.

5 OHSAS, *Occupational Health and Safety Management Systems: Requirements*, BS OHSAS 18001:2007.

6 In terms of accidental infection, toxicity or allergy, or unauthorized access, loss, theft, misuse, diversion or release of biological agents or valuable biological materials (VBMs).

7 VBMs has been defined by the WHO as biological materials that require administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, or the population from their potential to cause harm. A VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms, cell components, genetic elements and extraterrestrial samples. For further information see WHO, *Biorisk Management: Laboratory Biosecurity Guidance*, 2006.

8 OHSAS, *Occupational Health and Safety Management Systems: Requirements*, BS OHSAS 18001:2007.

9 See for example « Décret n° 2010-736 du 30 juin 2010 relatif aux micro-organismes et toxines » and « Arrêté du 30 juin 2010 fixant la liste des micro-organismes et toxines prévue à l'article L. 5139-1 du code de la santé publique ».

10 International Organization for Standardization (ISO), *Quality Management Systems: Requirements*, ISO 9001:2008.

11 ISO, *Environmental Management Standard: Requirements*, ISO 14001:2004.

12 ISO, *General Requirements for the Competence of Testing and Calibration Laboratories*, ISO/IEC 17025:2005.

13 ISO, *Medical Laboratories: Particular Requirements for Quality and Competence*, ISO 15189:2007.

14 For further information see OECD, *OECD series on principles of good laboratory practice and compliance monitoring*, document ENV/MC/CHEM(98)17, 21 January 1998.

15 ISO, *Quality Systems: Model for Quality Assurance in Production, Installation and Servicing*, ISO 9002:1994.

16 European Committee for Standardization (CEN), *Laboratory Biorisk Management Standard*, CEN Workshop Agreement, CWA 15793, 2008. This CEN workshop agreement can in no way be held as being an official standard developed by CEN and its members but can be used as a reference document.

17 OECD, *OECD Best Practice Guidelines for Biological Resource Centres*, 2007, p. 11.

18 The CABRI guidelines cover the characterization of strains with viability, purity, identity and stability.

19 Common acquisition criteria would include compiling details of: the name, other identifier or cell culture description; the depositor's name and address; the source, substrate or host from which the biological sample was isolated or derived; the geographical location of the isolate; the depositor's strain number or other collection number; assigning the sample a unique collection number; cell preservation or storage conditions; and hazard status.

Chapter 12
Case study I: biosafety and biosecurity in Pakistan

1 WHO, *Laboratory Biosafety Manual: Third Edition*, 2004.

2 Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety*, 2000.

3 For further information see G. Jaffe, "Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory System: An Analysis of Key Unresolved Issues", *Journal of Public Affairs*, vol. 5, no. 3–4, 2005, pp. 299–311; H. Mann, *The Cartagena Protocol on Biosafety: An analysis*, presented at "ASEAN Workshop on International Trade in ASEAN Agriculture and Forest Products and Measures to Align Trade and Environments", Bangkok, 1 June 2000; and Intergovernmental Committee for the Cartagena Protocol on Biosafety, *Capacity-building (Article 22, Article 28)*, document UNEP/CBD/ICCP/1/4, 10 October 2000.

4 See Pakistan Biosafety Rules 2005, *Notification*, document SRO (I) 336(I)/2005, 21 April 2005; and Pakistan Environmental Protection Agency, *National Biosafety Guidelines*, document Notification No. F.2(7)95-Bio, May 2005.

Chapter 13
Case Study II: the control of human pathogens in Canada

1 To follow the progress of these consultations being conducted by the Pathogen Regulation Directorate of the PHAC and development of HPTA policy documents, see <www.phac-aspc.gc.ca>.

Chapter 14
Views from the field: biosafety and biosecurity challenges in the Asia–Pacific region

1 A version of this article also appears in "Biosafety Professionals as Stakeholders in the BTWC", *Disarmament Forum*, no. 1, UNIDIR, 2011, pp. 30–32.

2 A–PBA, *Newsletter*, vol. 3, no. 2, 2010.

3 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008.

Chapter 15
Education, awareness-raising and codes of conduct

1 This chapter is introduced by Junko Horibe, an adviser to the Delegation to the Conference on Disarmament in Geneva.

2 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Oversight, education, awareness raising, and codes of conduct for preventing the misuse of bio-science and bio-technology*, document BWC/MSP/2008/MX/WP.21, 14 August 2008.

Chapter 16
Case study I: the Aum Shinrikyo's biological weapons terrorism in Japan

1 This paper is based on a draft thesis for the National Graduate Research Institute for Policy Studies, Tokyo, (forthcoming).

2 For a detailed account of events and court proceedings see the following books by K. Furihata: *Oumu Houtei-Guru no Shimobe Tachi Joukan* (Aum Court Trial, vol. 1, part I: The Servants to The Guru), 1998; *Oumu Houtei: Guru vs. Shinto, Joukan* (Aum Court Trial, vol. 2, part I: The Guru vs. The Followers), 1998; *Oumu Houtei 3: chiryoushou Daijin Hayashi Ikuo* (Aum Court Trial, vol. 3, Aum's Minister of Cure, Ikuo Hayashi), 1998; *Oumu Houtei 7: Jotei Ishii Hisako* (Aum Court Trial, vol. 7, Empress Hisako Ishii), 2001; *Aum Houtei 9: Chouhoushou Choukan Inoue Yoshihiro* (Aum Court Trial, vol. 9, Aum's Minister of Intelligence Yoshihiro Inoue), 2002; *Oumu Houtei 12: Sarin wo Tsukutta Otokotachi* (Aum Court Trial, vol. 12, The Men Who Produced Sarin), 2003.

3 K. Hayakawa, *Watashi ni totte Aum toha Nandattanoka* (What Aum Meant to Me), 2005, p. 165.

4 For a detailed account of events and court proceedings see the following books by M. Shakaibu (ed.): *Oumu Kyouso Houtei Zen Kiroku 5* (Records of Court Testimonies in the Trial of the Aum Leader, vol. 5), 2000; *Oumu Kyouso Houtei Zen Kiroku 7* (Records of Court Testimonies in the Trial of the Aum Leader, vol. 7), 2002; *Oumu Kyouso Houtei Zen Kiroku 8* (Records of Court Testimonies in the Trial of the Aum Leader, vol. 8), 2003.

5 In addition to the court proceedings, see H. Takahashi et al., "*Bacillus anthracis* Incident, Kameido, Tokyo, 1993", *Emerging Infectious Diseases*, vol. 10, no. 2, 2004.

6 T. Hayasaka, *Oumuha Naze Bousou Shitaka* (Why Aum Went Out Of Control), 1998, pp. 271.

7 K. Hayakawa, *Watashi ni totte Aum toha Nandattanoka* (What Aum Meant to Me), 2005, p. 188–90.

8 S. Fujita, *Shuukyou Jiken no Uchimaku* (Inside Stories of Religion-Related Incidents), 2008, pp. 282–83.

9 T. Takeoka, *"Oumu Shinrikyou Jiken" Kanzen Kaidoku* (Complete Decoding of "The Aum Shinrikyo Incidents"), 1999, p. 39.

10 S. Fujita, *Shuukyou Jiken no Uchimaku* (Inside Stories of Religion-Related Incidents), 2008, p. 270.

11 Ibid, pp. 281–90. For an explanation of shaman disease see K. Naka et al., "Yuta (Shaman) and Community Mental Health on Okinawa", *International Journal of Social Psychiatry*, vol. 31, no. 4, 1985, pp. 267–73.

12 K. Furukawa and N. Noro, "The Nexus Between Illicit Networks and WMD Proliferation: The Case Study of North Korea", in C. Zimke-Dickens and J. Droogan (eds), *Asian Transnational Security Challenges: Emerging Trends, Regional Visions*, 2010, pp. 167–82.

13 A. Misawa, *Sousa Ikka Hiroku* (Classified Record of the First Investigation Division of Tokyo Metropolitan Police Agency), 2004, p. 201.

14 Remarks of S. Endo in *Hi Izuru Kuni, Wazawai Chikashi* (The Country with A Rising Sun, Disaster Approaching), 1995, pp. 198–99.

Chapter 17
Case study II: an Australian perspective on awareness-raising, education and codes of conduct

1 For a detailed discussion see T. Dunworth, R. Mathews and T. McCormack, "National Implementation of the Biological Weapons Convention", *Journal of Conflict and Security Law*, vol. 11, no. 1, 2006, pp. 93–118.

2 Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final declaration*, document BWC/CONF.II/13/II, 30 September 1986, p. 4.

3 Surveys undertaken by the University of Bradford in 2005 concluded that the vast majority of life scientists are unaware of the provisions of the BWC and potential dual-use aspects of their work. For more information see M. Dando and B. Rappert, "Codes of Conduct for the Life Sciences: Some Insights from UK Academia", Briefing Paper No. 16, University of Bradford, 2005.

4 R. Mathews, "WMD Arms Control Agreements in the Post-September 11 Security Environment: Part of the 'Counter-terrorism Toolbox'", *Melbourne Journal of International Law*, vol. 8, no. 2, 2007, pp. 292–310.

5 For a summary report of recent advances in biological sciences, including in computational biology, genomics, proteomics, systems biology and synthetic biology, see Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Background information document on new scientific and technological developments relevant to the Convention*, document BWC/CONF.VI/INF.4, 28 September 2006.

6 These include experiments that would: demonstrate how to render a vaccine ineffective; confer resistance to therapeutically useful antibiotics or antiviral agents; enhance the virulence of a pathogen or render a non-pathogen virulent; increase the transmissibility of a pathogen; alter the host range of a pathogen; enable the evasion of diagnostic and detection modalities; and enable the weaponization of a biological agent or toxin. See National Research Council, *Biotechnology Research in an Age of Terrorism*, 2004, (commonly known as the Fink Report, after G. Fink).

7 Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.V/17, 2002.

8 Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006, p. 21.

9 The important roles of codes in facilitating awareness-raising and promoting a culture of responsibility have been reinforced in subsequent Meetings of States Parties. For example see R. Mathews and J. Webb, "The Biological Weapons Convention Three-Year Program of Work 2005: Codes of Conduct for Scientists", in R. Mathews (ed.), *Proceedings of the Biological Weapons Convention Regional Workshop: Co-hosted by the Governments of Australia and Indonesia*, 2005, pp. 175–185; and Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008.

10 This could be a short aspirational code, containing general principles and referring to ethical norms (comparable to the Hippocratic Oath for medical practitioners).

11 There could be new codes or new elements relevant to the BWC which could be added to existing codes.

[12] These are more detailed codes applicable to a particular workplace. Scientists in the workplace could develop a new workplace code or add BWC-related elements to an existing workplace code (in effect, this would be a "bottom-up" approach). See Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Codes of conduct for scientists: considerations during a BWC regional workshop and subsequent reflections*, document BWC/MSP/2005/MX/WP.35, 24 June 2005.

[13] AusBiotech, *Biotechnology Industry: Code of Conduct*, 2005, p. 9. AusBiotech also has a number of "Members Commitments" which include "Members will ensure that staff and colleagues are made aware of this Code of Conduct and other standards, guidelines and laws relevant to the safe and ethical conduct of biotechnology activities".

[14] These two examples also illustrate how different scientific societies name their society codes: Code of Conduct in the case of AusBiotech, and Code of Ethics in the case of the ASM. This variation in nomenclature can cause confusion, which is why we choose to call this type of code a "scientific society code".

[15] ASM, *Code of Ethics*, at <www.theasm.org.au/ABOUT_US/governance>.

[16] The document, which was originally provided to participants at the BWC regional workshop in Bali, in February 2006, was based on the elements of a workplace code which had been developed by scientists at Australia's Defence Science and Technology Organisation Biodefence facility in November 2005.

[17] For a summary report of some of the recent developments in codes of conduct, see Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Developments in codes of conduct since 2005*, document BWC/MSP/2008/MX/INF.2, 26 June 2008.

[18] Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008.

[19] Security Council, *Resolution 1540 (2004)*, UN document S/RES/1540 (2004), 28 April 2004.

[20] This is despite the fact that the Review Conferences have encouraged governments to undertake the necessary awareness-raising activities in order that relevant scientific communities become aware of all such laws and regulations. For example, the Sixth Review Conference encouraged states parties "to take necessary measures to promote awareness amongst relevant professionals of the need to report activities conducted within their territory or under their jurisdiction or under their control that could constitute a violation of the Convention or related national criminal law". See Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and

Toxin Weapons and on Their Destruction, *Final document*, document BWC/CONF.VI/6, 2006, p. 11.

21 This is unfortunate as there is a clear responsibility of facility managers to ensure that their workers are fully aware of all domestic laws and regulations governing the pathogens and toxins they are using in their workplace.

22 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Raising awareness: approaches and opportunities for outreach*, document BWC/MSP/2005/MX/WP.29, 21 June 2005.

23 For further information see Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Communication issues associated with implementation of the SSBA Regulatory Scheme*, document BWC/MSP/2008/MX/WP.30, 21 August 2008.

24 Available at <www.health.gov.au/ssba>.

25 Targeted stakeholders include the facilities working with a number of pathogens and toxins of relevance to proliferation or terrorism concern, including *Bacillus anthracis*, ricin and *Yersinia pestis*.

26 For example see R. Mathews, "Codes of Conduct for Scientists", *Defence Export Controls Bulletin*, Issue 2, 2006, pp. 7–8.

27 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Australia's National Framework for the Development of Ethical Principles in Gene Technology and the Biological Weapons Convention (BWC)*, document BWC/MSP/2008/MX/WP.31, 21 August 2008.

28 Available at <www.ogtr.gov.au>.

29 C. Enemark, "Raising Awareness Among Australian Life Scientists", in B. Rappert (ed.), *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, 2010, pp. 131–48.

Chapter 18
Case study III: the Dutch experience of a code of conduct on biosecurity and further

1 This is an updated version of a presentation by the Netherlands, "Towards a Code of Conduct on Biosecurity and further ...", presented at the Meeting of Experts, 22 August 2008.

2 IAP, *IAP Statement on Biosecurity*, 2005.

3 B. Rappert, *Towards a Life Sciences Code: Countering the Threats from Biological Weapons*, Briefing Paper No. 13, University of Bradford, 2004.

4 NSABB, "International Roundtable on Dual Use Life Sciences Research", Bethesday, 25–27 February 2007. See also NSABB, *Codes of Conduct Working Group: Progress Report*, 2006.

5 For the full text of the Code of Conduct, see KNAW, *A Code of Conduct for Biosecurity: Report by the Biosecurity Working Group*, 2007, pp. 11–12.

Chapter 19
Views from the field I: encouraging responsible stewardship of the life sciences

1 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of Experts*, document BWC/MSP/2008/MX/3, p. 1.

2 NRC, *Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention: Summary of an International Workshop*, 2011.

3 For example see J. Lederberg, *Emerging Infections: Microbial Threats to Health in the United States*, 1992.

4 Created in 1980 to keep communication open between US and Soviet scientists on technical issues related to nuclear arms control, CISAC has 30 years of experience working on issues of science, technology, security and non-proliferation with international partners. CISAC has served as an impartial and unbiased bridge between the US and other governments at critical times when government communications were not feasible. CISAC draws from the best scientific, technical, engineering and medical talent to advise the US government, contribute to the work of non-governmental organizations (NGOs), and inform the public about issues related to international security and arms control.

5 Funding for the project came from the Alfred P. Sloan Foundation and the Nuclear Threat Initiative.

6 NRC, *Biotechnology Research in an Age of Terrorism*, 2004.

7 NRC, *Seeking Security: Pathogens, Open Access, and Genome Databases*, 2004.

8 NRC, *Globalization, Biotechnology, and the Future of the Life Sciences*, 2006.

9 For this reason the NRC pays particular attention to the ways in which reports on similar topics may change over time. Clearly, new evidence or advances in science and technology should affect such messages, but major efforts are made to ensure that changes in recommendations from one report to another have been impervious to shifting political winds.

10 For examples see NRC, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities*, 2007; and NRC, *Responsible Research with Biological Select Agents and Toxins*, 2009.

[11] This section draws heavily on the background material presented in two NRC publications: *The 2nd International Forum on Biosecurity: Summary of an International Meeting, Budapest, Hungary, March 30 to April 2, 2008*, 2009; and *Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences*, 2010.

[12] See B. Rappert, *Towards a Life Science Code: Countering the Threats from Biological Weapons*, Briefing Paper No. 13, University of Bradford, 2004.

[13] The IAP General Assembly had received proposals in December 2003 from the ICGEB to collaborate on preparing a code of conduct. It became clear towards the end of 2004, however, that the process needed to create and then gain endorsement of an IAP statement could not proceed quickly enough to meet the ICGEB's desire to fulfil the request from the United Nations to have a completed code in time for the BWC Meeting of Experts in June 2005. The two efforts therefore went forward separately.

[14] NRC, *The 2nd International Forum on Biosecurity: Summary of an International Meeting, Budapest, Hungary, March 30 to April 2, 2008*, 2009, pp. 15–16.

[15] This was also the period in which ICSU dissolved its standing Committee on Freedom in the Conduct of Science and created the new Committee on Freedom *and Responsibility* [emphasis added] in the Conduct of Science. While retaining its long-standing commitment to the principles of the universality of science, such as the rights of scientists to travel, associate and communicate freely, the "new Committee differs significantly from its predecessors in that it has been explicitly charged with also considering the responsibilities of scientists". See ICSU, *Freedom, Responsibility and Universality of Science*, 2008, p. 2.

[16] IAP, *IAP Statement on Biosecurity*, 2005. All statements, documents and presentations made during the meetings can be found on the BWC website at <www.unog.ch/bwc>.

[17] IUBMB, *Code of Ethics of the International Union of Biochemistry and Molecular Biology*, 2005.

[18] IUMS, *IUMS Code of Ethics Against Misuse of Scientific Knowledge, Research and Resources*, 2006.

[19] NRC, *The 2nd International Forum on Biosecurity: Summary of an International Meeting, Budapest, Hungary, March 30 to April 2, 2008*, 2009, p. 2.

[20] The Polish Academy chaired the IAP Working Group in early 2010.

[21] NRC, *Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences*, 2010, p. 9

[22] Ibid., p. 2.

Chapter 20
Views from the field II: the IUPAC and the oversight of science

1 Note from the Editor: There is on overlap in the scope of the Chemical Weapons Convention and the Biological Weapons Convention as both conventions cover certain toxins. Therefore, certain efforts to address chemical weapons are directly related to efforts to deal with biological weapons. In addition, those active in efforts to address chemical weapons have experience in undertaking similar outreach, education and awareness-raising activities.

2 The states of the 56 NAOs are: Australia, Austria, Bangladesh, Belgium, Brazil, Bulgaria, Canada, Chile, China, Croatia, Cuba, Cyprus, the Czech Republic, Denmark, Egypt, Ethiopia, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kuwait, Luxembourg, Malaysia, the Netherlands, New Zealand, Norway, Pakistan, Poland, Portugal, Puerto Rico, the Republic of Korea, the Russian Federation, Serbia, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Turkey, Ukraine, the United Kingdom, the United States and Uruguay.

3 The three states linked to IUPAC as ANAOs are: Argentina, Nigeria and Venezuela.

4 See G. Parshal et al., "Impact of Scientific Developments on the Chemical Weapons Convention", *Pure and Applied Chemistry*, vol. 74, no. 12, 2002, pp. 2229–352.

5 IUPAC, "The Impact of Advances in Science and Technology on the Chemical Weapons Convention", workshop, Zagreb, 22–25 April 2007.

6 See M. Balali-Mood et al., "Impact of Scientific Developments on the Chemical Weapons Convention", *Pure and Applied Chemistry*, vol. 80, no. 1, 2008, pp. 175–200.

7 Participants came from Argentina, Australia, Belgium, Brazil, Canada, Croatia, the Czech Republic, Finland, France, Germany, India, Iran, Japan, Nigeria, the Netherlands, Norway, Poland, the Republic of Korea, Romania, the Russian Federation, Singapore, Slovenia, South Africa, Spain, Switzerland, Turkey, Ukraine, the United Kingdom and the United States.

8 Conference of the State Parties to Review the Operation of the Chemical Weapons Convention, *Note by the Director-General: report of the Scientific Advisory Board on developments in science and technology*, document RC–2/DG.1, 28 February 2008, p. 20.

9 Conference of the State Parties to Review the Operation of the Chemical Weapons Convention, *Opening Statement by the Director-General to the Second Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention*, document RC–2/DG.2, 7 April 2008, p. 11.

10 See G. Pearson and P. Mahaffy, "Education, Outreach, and Codes of Conduct to Further the Norms and Obligations of the Chemical Weapons Convention", *Pure and Applied Chemistry*, vol. 78, no. 11, 2006, pp. 2169–92.
11 For the final report see IUPAC, "Chemical Education: Responsible Stewardship", *Chemistry International*, vol. 28, no. 2, 2006, pp. 23–25.
12 For the final report see IUPAC, "Multiple Uses of Chemicals: Clear Choices or Dodgy Deals?", *Chemistry International*, vol. 29, no. 6, 2007, p. 23.
13 For further information see <www.iupac.org/web/ins/2007-022-2-020>.

Chapter 21
Views from the field III: awareness-raising seminars

1 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008, pp. 6–7.
2 While it was suggested that any such system might provide a necessary guard against outside interference in science, raise awareness of issues relating to potential misuse and act as part of the needed reforms of wider university practices, the majority of responses were critical in nature. Such systems were deemed unworkable because of the impossibility of knowing the future implications of research, ineffective because terrorists would circumvent them, misplaced because British universities were not the types of places that should be causes of concern, and counterproductive because of the amount of existing regulations.
3 M. Dando and B. Rappert, *Codes of Conduct for the Life Sciences: Some Insights from UK Academia*, Bradford Briefing Paper No. 16, 2005.
4 A fuller examination of the methods and rationale behind the seminars is given in B. Rappert, *Biotechnology, Security and the Search for Limits: An Inquiry into Research and Methods*, 2007.
5 B. Rappert, M. Chevrier and M. Dando, *In-Depth Implementation of the BTWC: Education and Outreach,* Bradford Review Conference Paper No. 18, 2006.
6 For further information on the seminars and other publications see <http://projects.exeter.ac.uk/codesofconduct/BiosecuritySeminar/Education/index.htm>.
7 For more information of this round of the seminars, see B. Rappert, *Experimental Secrets: International Security, Codes, and the Future of Research*, 2009.
8 B. Rappert (ed.), *Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons*, 2010.

Chapter 22
Views from the field IV: online train-the-trainer modules in dual-use bioethics and biosecurity

1 For further information see <www.brad.ac.uk/bioethics/TraintheTrainer/>.

2 See M. Dando and B. Rappert, *Codes of Conduct for the Life Sciences: Some Thoughts from UK Academia*. Briefing Paper No. 16, University of Bradford, 2005.

3 For further information see: G. Mancini and J. Revill, *Fostering the Biosecurity Norm: Biosecurity Education for the Next Generation of Life Scientists*, Landau Network-Centro Volta and Bradford Disarmament Research Centre, 2008; and M. Minehata and N. Shinomiya, *Biosecurity Education: Enhancing Ethics, Securing Life and Promoting Science: Dual-Use Education in Life-Science Degree Courses at Universities in Japan*, National Defense Medical College and the University of Bradford, 2009.

4 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2008/5, 12 December 2008, p. 7. For further information see S. Whitby and M. Dando, *Effective Implementation of the BTWC: The Key Role of Awareness Raising and Education*, Review Conference Paper No. 26, University of Bradford, 2010.

5 Meeting of Foreign Ministers, *Statement on the 7th Review Conference for the Biological and Toxin Weapons Convention*, press release, 14–15 March 2011.

6 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare.

7 The Bradford Disarmament Research Centre along with the National Defense Medical College and the Landau Network Centro Volta have developed an EMR designed to support life scientists and educators in learning about biosecurity and dual-use issues and also in building educational material for teaching students. English and other language versions of the biosecurity education module are also available.

8 National Focal Point for the Biological and Toxin Weapons Convention, *National Guidelines for the Development of a Code of Conduct for Life Scientists*, Government of Pakistan, 2010.

9 Whilst the report focused principally on synthetic biology, its findings and recommendations for building a culture of responsible conduct can be equally applied across life science disciplines. See Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, 2010.

Chapter 23
Addressing the spectrum of biorisks

1 This chapter is adapted from remarks made by Ambassador Grinius in his role as Chairman, delivered at the Biosafety and Biosecurity International Conference 2009, Casablanca, 2–3 April 2009.

Chapter 24
Providing assistance and coordinating response following the use of a biological weapon

1 See Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2010/6, 17 December 2010.
2 M. Ryan, "WHO's Response in the Case of an Alleged Use of a Biological Agent", WHO presentation to the Meeting of Experts, 25 August 2010. A full list of all presentations made at the Meeting of Experts can be found at <www.unog.ch/bwc/docs>.
3 J. De Baerdemaeker, "After Action Report Bioterrorism TTEX 'BIOSHIELD'", INTERPOL presentation to the Meeting of Experts, 25 August 2010.
4 FBI and CDC, "Joint Public Health and Law Enforcement Investigations: 'Enhancing Relationships to Improve Readiness'", presentation to the Meeting of Experts, 24 August 2010.
5 A. Ochieng Aluoch, "Kenya's Response to an Anticipated Bioterrorism Attack", National Biological and Toxin Weapons Committee presentation to the Meeting of Experts, 24 August 2010.

Chapter 25
Reducing biological risks by building capacity in health security

1 WHO, *International Health Regulations (2005)*, 2005, p. 10.
2 The target audience of such training is public-health authorities and policymakers, health-care managers and workers, as well as laboratory management and staff in developing and transitional countries.
3 WHO, *Laboratory Biosafety Manual*, 2004; WHO, *Biorisk Management: Laboratory Biosecurity Guidance*, 2006.

Chapter 26
International efforts to reduce threats from animal pathogens

1 FAO, OIE and WHO, *Sharing Responsibilities and Coordinating Global Activities to Address Health Risks at the Animal–Human–Ecosystem Interfaces*, 2010.

Chapter 27
INTERPOL table-top exercise BioShield Americas 2010

1 Argentina, Bolivia, Brazil, Chile, Colombia, the Dominican Republic, Grenada, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, and Uruguay.

Chapter 28
International coordination: responding to the use of biological weapons

1 There has been some excellent work done at the national level on how public health and security responses interact. See for example US Federal Bureau of Investigation and United States Centers for Disease Control and Prevention, "Joint Public Health and Law Enforcement Investigations: 'Enhancing Relationships to Improve Readiness'", presentation to the Meeting of Experts, 24 August 2010. This and other presentations can be found at <www.unog.ch/bwc/docs>.

Chapter 29
Case study: implementation of the Biological Weapons Convention in Kenya

1 Security Council, *Resolution 1540 (2004)*, UN document S/RES/1540 (2004), 28 April 2004.

2 The committee comprises of representatives from the National Quality Control Laboratory, the State Law Office, the University of Nairobi and the ministries of: agriculture, defence, foreign affairs, medical services, and public health and sanitation. The representative from the University of Nairobi was elected Chair of the NBTWC.

Chapter 30
Views from the field I: Regional infectious disease surveillance networking

1 WHO, *International Health Regulations (2005)*, 2008.

[2] For further information see: Institute of Medicine, *Infectious Disease Movement in a Borderless World*, 2010; and *PLoS Medicine* Editors, "How is WHO Responding to Global Public Health Threats?" *PLoS Medicine*, vol. 4, no. 5, 2007, p. e197.

[3] Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009, pp. 5–6.

[4] For further information see L. Gresham et al., "Trust Across Borders: Responding to 2009 H1N1 Influenza in the Middle East", *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol. 7, no. 4, 2009, pp. 399–404.

[5] Food and Agricultural Organization of the United Nations et al., *Contributing to One World, One Health: A Strategic Framework for Reducing Risks of Infectious Diseases at the Animal-Human-Ecosystems Interface*, 2008.

[6] M. Baker and D. Fidler, "Global Public Health Surveillance under New International Health Regulations", *Emerging Infectious Diseases*, vol. 12, no. 7, 2006, pp. 1058–65.

[7] J. Sturtevant, A. Anema and J. Brownstein, "The New International Health Regulations: Considerations for Global Public Health Surveillance", *Disaster Medicine and Public Health Preparedness*, vol. 1, no. 2, 2007, pp. 117–21.

[8] A. Kimball et al., "Regional Infectious Disease Surveillance Networks and Their Potential to Facilitate the Implementation of the International Health Regulations", *Medical Clinics of North America*, vol. 92, no. 6, 2008, pp. 1459–71.

[9] Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009, p. 7.

[10] Ibid.

[11] National Security Council, *National Strategy for Countering Biological Threats*, 2009, p. 4.

[12] Ibid., p. 6.

[13] See <http://geneva.usmission.gov/2009/12/09/tauscher-bwc/>.

[14] Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Report of the Meeting of States Parties*, document BWC/MSP/2009/5, 16 December 2009, p. 8.

LIST OF ABBREVIATIONS

AfD	Agence française de développement
ABSA	American Biological Safety Association
ANAO	Associate National Adhering Organization
A–PBA	Asia–Pacific Biosafety Association
ASM	Australian Society for Microbiology
BDRC	Bradford Disarmament Research Centre
BERISS	Biological Emergency Response and Investigation Support System
BRC	biological resource centre
BSL	biosafety level
BWC	Biological Weapons Convention
CABRI	Common Access to Biological Resources and Information
CBM	confidence-building measure
CBRN	chemical, biological, radiological and nuclear
CDC	United States Centers for Disease Control and Prevention
CEN	European Committee for Standardization
CISAC	Committee on International Security and Arms Control
CWC	Chemical Weapons Convention
DECO	Defence Export Control Office
DNA	deoxyribonucleic acid
DSGL	Defence and Strategic Goods List
EAC	East African Community
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EHEC	enterohemorrhagic *Escherichia coli*
EMR	education module resource
FAO	Food and Agriculture Organization of the United Nations
FBI	US Federal Bureau of Investigation
FMD	foot-and-mouth disease
G8	Group of Eight
GF-TADs	Global Framework for Progressive Control of Transboundary Animal Diseases
GHSI	Global Health Security Initiative
GLEWS	FAO/OIE/WHO Global Early Warning System
GLP	good laboratory practices

GMO	genetically modified organism
GTEC	Gene Technology Ethics Committee
HIV	human immunodeficiency virus
HPIRs	Human Pathogens Importation Regulations
HPTA	Human Pathogens and Toxins Act
IAMP	InterAcademy Medical Panel
IAP	InterAcademy Panel on International Issues
IBC	institutional biosafety committee
IBWG	International Biosafety Working Group
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICLS	International Council for the Life Sciences
ICRC	International Committee of the Red Cross
ICSU	International Council for Science
ICT	information and communications technology
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
IMS	integrated management system
INTERPOL	International Criminal Police Organization
ISBI	International Security and Biopolicy Institute
ISO	International Organization for Standardization
ISS	Institute for Security Studies
ISU	Implementation Support Unit
IUBMB	International Union of Biochemistry and Molecular Biology
IUBS	International Union of Biological Sciences
IUMS	International Union of Microbiological Societies
IUPAC	International Union of Pure and Applied Chemistry
KNAW	Royal Netherlands Academy of Arts and Sciences
LBG	Laboratory Biosafety Guidelines
MBDS	Mekong Basin Disease Surveillance
MECIDS	Middle East Consortium on Infectious Disease Surveillance
NAO	National Adhering Organization
NAS	National Academy of Sciences
NBC	National Biosafety Committee
NBTWC	National Biological and Toxin Weapons Committee
NCB	National Commission on Biotechnology
NCST	National Council for Science and Technology
NCTb	National Coordinator for Counterterrorism

NCGLS	National Core Group in Life Sciences
NGO	non-governmental organization
NHS Act	National Health Security Act 2007
NIM	national implementation measures
NRC	National Research Council
NSABB	National Science Advisory Board for Biosecurity
NTI	Nuclear Threat Initiative
OAS	Organization of American States
OECD	Organisation for Economic Co-operation and Development
OFFLU	OIE–FAO joint network of expertise on animal influenza
OHSAS	Occupation Health and Safety Assessment Series
OIE	World Organisation for Animal Health
OLS	Office of Laboratory Security
OPCW	Organization for the Prohibition of Chemical Weapons
PAHO	Pan American Health Organization
PHAC	Public Health Agency of Canada
PIC	prior informed consent
POPs	persistent organic pollutants
PVS	performance of veterinary services
QSE	quality, security, environment
SACIDS	Southern African Centre for Infectious Disease Surveillance
SARS	severe acute respiratory syndrome
SOP	standard operating procedure
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SSBA	security sensitive biological agent
TTX	table-top exercise
UNICRI	United Nations Interregional Crime and Justice Research Institute
UNIDIR	United Nations Institute for Disarmament Research
UNODA	United Nations Office for Disarmament Affairs
VBM	valuable biological material
VERTIC	Verification Research, Training and Information Centre
WAHID	World Animal Health Information Database
WAHIS	World Animal Health Information System
WMD	weapon of mass destruction
WHO	World Health Organization
WTO	World Trade Organization

Implementation of the obligations of the Biological Weapons Convention (BWC) has lagged seriously behind other disarmament and non-proliferation regimes. Without an international organization to shoulder the burden, states have been left alone to establish ad hoc national arrangements. The two most recent work programmes within the BWC framework have helped to harmonize national approaches and focused on building capacity to translate international obligations into effective national action. States have begun to identify common ground in their approaches, to learn from each other's experiences and create a community of actors dedicated to ensuring that the life sciences are not used to cause deliberate harm.

Over the last decade it has become increasingly clear that effective action will require a concerted effort from all those who can play a role in ensuring that the life sciences continue to be used safely, securely and solely for beneficial purposes. This book gathers together many of the best contributions from the recent work within the BWC framework and provides expert reviews of key themes, case studies of interesting national approaches, as well as unique perspectives from the ground. It is a practical tool for implementing the convention, an introductory guide to current best practice at the health/security interface and adds to the historical record of this important international instrument.

Designed and printed by the Publishing Service, United Nations, Geneva
GE.11-01362 — September 2011 — 2,230 — **UNIDIR/2011/7**