

Preventing Biological Threats: What You Can Do

Editors

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A Guide to Biological Security Issues and How to Address Them

Credits

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List of Acronyms

AAAS American Association for the Advancement of Science

AHG Ad Hoc Group (of the Biological Weapons Convention)

AgSAS Agricultural Select Agent Services

ALAT Assistant Legal Attaches

AusAID Australian Agency for International Development

BBSRC Biotechnology and Biological Sciences Research Council (UK)

BCU Biological Countermeasures Unit (of the FBI)

BBIC Biosafety and Biosecurity International Consortium

BMU Biorisk Management Unit (Jordan MOH)

BRMTD BioRisk Management Training Division (of MENA)

BSL 3 Biosafety Laboratory Level 3

BSATs Biological Select Agents and Toxins

BTPU Bioterrorism Prevention Programme (of INTERPOL)

BTWC Biological and Toxin Weapons Convention (also known as the BWC Biological Weapons Convention)

BW Biological Weapons

CB Chemical/Biological

CBB Centre for Biosecurity and Biopreparedness (Denmark)

CBM Confidence Building Measure

CBRN CoE Chemical, Biological, Radiological and Nuclear Centres of Excellence

CBRN Chemical, Biological, Radiological and Nuclear

CBRNE Chemical Biological Radiological Nuclear Explosive

CBW Chemical/Biological Weapons

CDC Centers for Disease Control (US)

CIA Central Intelligence Agency

CITES Convention on International Trade on Endangered Species

CMC Cooperative Monitoring Centre

CODEX Codex Alimentarius Commission

CORDS Connecting Organisation for Regional Disease Surveillance

CRIPR/Cas9 Clustered Regularly Interspaced Short Palindrome Repeats (CRISPR)
Cas9 endonuclease systems

CW Chemical Weapon

CWC Chemical Weapons Convention

DNA Deoxyribonucleic acid

rDNA Recombinant DNA Techniques

DURC Dual Use Research of Concern

EBRF European Biosecurity Regulators Forum

EMPRESS Emergency Prevention System for Transboundary Animal and Plant Pests
and Diseases (FAO)

EMRO Eastern Mediterranean Regional Office (of WHO)

ESV European Society for Virology

EU European Union

EVD Ebola Virus Disease

FAO UN Food and Agriculture Organization

FBI Federal Bureau of Investigation (United States)

FIT Field Investigation Team

FVR Foundation for Vaccine Research

GERC Global Ebola Response Coalition

GHSA Global Health Security Agenda

GHSI Global Health Security Initiative

GMOs Genetically Modified Organisms

GP Global Partnership Against WMD

HAZMAT Hazardous Material

HIV Human Immunodeficiency Virus

HHS Department of Health and Human Services (US)

HPAI Highly Pathogenic Avian Influenza (e.g. H5N1)

IAEA International Atomic Energy Agency

IAP InterAcademy Panel

IBC Institutional Biosafety Committee

ICLS International Council for the Life Sciences

IFBA International Federation of Biosafety Associations

iGEM International Genetically Engineered Machine (Competition)

IHR International Health Regulations

INTERPOL International Criminal Police Organisation

iRAT Individual Readiness Assurance Test

ISP Inter Sessional Work Programme (of the Biological and Toxin Weapons Convention)

ISIS/ISIL Islamic State of Iraq and the Levant

ISU Implementation Support Unit (of the Biological and Toxin Weapons Convention)

IUBMB International Union of Biochemistry and Molecular Biology

IUPAC International Union of Pure and Applied Chemistry

JUST Jordan University of Science and Technology

KNAW Netherlands Academy of Arts and Sciences

LMICs Low/Middle Income Countries

LMOs Living Modified Organisms

MDMA 3, 4-methylenedioxy-methamphetamine (psychoactive drug)

MEAs Multilateral Environmental Organisations

MENA Middle East and North Africa

MERS Middle East Respiratory Syndrome

MESIS Middle East Scientific Institute for Security (Jordan)

MMR Measles/Mumps/Rubella (Vaccine)

MOH Ministry of Health (Jordan)

MRC Medical Research Council (UK)

MSP Meeting of States Parties (of the Biological and Toxin Weapons Convention)

MX Meeting of Experts (of the Biological and Toxin Weapons Convention)

NAS National Academy of Science (US)

NATO North Atlantic Treaty Organisation

NCARE National Centre for Agricultural Research Extension (Jordan)

NCBs National Central Bureaus (of the Police)

NCBD National Centre for Biological Defence (Denmark)

NCSCM National Centre for Security and Crisis Management (Jordan)

NGO Non-Governmental Organisation

NGS Next Generation Sequencing

NIH National Institutes of Health (US)

NRC National Research Council (US)

NPT Nuclear Non-Proliferation Treaty

NSABB National Science Advisory Board for Biosecurity (US)

ODS Ozone Depleting Substances

OIE World Organisation for Animal Health

OPCW Organisation for the Prohibition of Chemical Weapons

PHBC Princess Haya Biotechnology Centre

PIN Personal Identification Number (Code)

PRPs Personnel Suitability/ Reliability Programmes

RKI Robert Koch Institute

RSC Responsible Conduct of Science

RSS Royal Scientific Society (Jordan)

SARS Severe Acute Respiratory Syndrome

SAB Scientific Advisory Board (of the Chemical Weapons Convention)

SB Synthetic Biology

SC Security Council (of the United Nations)

SEB Staphylococcus Enterotoxin B

S³oMMET Safe, Secure Surveillance of Microbiological Material and Emerging Technology

SRA Security Risk Assessment

SSI Statens Serum Institut (Denmark)

SWAPO South West Africa Peoples' Organisation

TBL Team Based Learning

tRAT Team Readiness Assurance Test

TRC Truth and Reconciliation Commission

TTX Table Top Exercise

TW Toxin Weapon

UNEP United Nations Environmental Programme

UNICEF United Nations Children's Fund

UNODC United Nations Office on Drugs and Crime

UNSCR 1540 United Nations Security Council Resolution 1540

US United States (of America)

USG United States Government

USDA United States Department of Agriculture

VECTOR State Research Center of Virology and Biotechnology (Russian Federation)

VEE Venezuelan Equine Encephalitis

VERTIC Verification Research, Training and Information Centre (London)

VX A Nerve Gas

WHO World Health Organization

WMD Weapons of Mass Destruction

WMDD Weapons of Mass Destruction Directorate (FBI)

WTO World Trade Organization

WWI World War One

WWII World War Two

XDR-TB Extensively Drug Resistant Tuberculosis

Acknowledgements

In order for responsible conduct in regard to all aspects of biological security to become an essential part of the norm in the life and associated sciences, there will have to be numerous developments in awareness raising, education and practice amongst this scientific community. The production of this book and the Team Based Learning exercises in the accompanying Handbook are intended to be one contribution to the development of the norm. This book was produced during the period from the autumn of 2014 through to the autumn of 2015 and involved three meetings of the authors: the first to discuss chapter outlines and summaries, the second to discuss draft chapters and the third to discuss the final chapters. We would like to thank all of the authors for producing their chapters on a tight time schedule and for attending the meetings in Bradford and Copenhagen in order to contribute to the discussions. We would also like to thank the science education specialists, Jay Labov, Simon Twedell and Mike Arnold who, right at the start asked all the critical questions about who the book was intended for, and how that audience was to be reached effectively. We hope that they can detect their influence in the final product. We would also like to thank other experts who kindly agreed to critically read through the almost final text for us on a very tight schedule. We have done our best to incorporate their suggestions in this final version. We are also much indebted to Ambassador Paul van den IJssel and HRH Princess Sumaya bint El Hassan for agreeing to write the Preface and Foreword to the book. Finally, we would like to thank the officials of the governments of Canada and the UK who provided us the grant that enabled us to carry out the project.

From the start, the aim was to produce information that would be freely accessible on the internet, so that it could be widely available for anyone who wanted to use it to help improve biological security around the world. It should be understood that we believe that biological security must be based first on proper laboratory biosafety and laboratory biosecurity. What this book and the accompanying exercises are intended to contribute to is an understanding of the problems of wider biological security beyond the laboratory door, and the external aspects of responsible conduct beyond the more familiar aspects of the responsible conduct of science. Our original grant included funding for a translation into Arabic and we hope that people who find the information useful will consider translations into other languages. The Team Based Learning exercises, as we discovered when we investigated their use in teaching life scientists at Bradford University in the UK, are easily replicated and therefore form a very efficient method of conveying the key points of the chapters. We would be more than happy to help with questions about how the exercises can be carried out. Naturally, we would also welcome suggestions about how both of these sets of texts can be improved and made more useful in the future.

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Bradford, December, 2015

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Preface

The outbreak of Ebola in West Africa in 2014 has underlined the risks posed by outbreaks of highly virulent and deadly diseases, whether caused naturally, accidentally or deliberately. It also emphasised the responsibility of all those engaged in the life sciences, whether in government, industry or academia, to ensure that research is done safely and securely.

This book, *Preventing Biological Threats*, is intended to raise awareness and knowledge of biological security of everyone active in the life sciences, ranging from those engaged in research to those engaged in management and policy-making, both nationally and internationally. The advances in biotechnology over the past decades and in the future have brought and will bring significant benefits to humankind, animals and plants -- however, these advances also bring risks that we need to be aware of and ensure that they cause no harm.

The continuing debate about the potential danger of carrying out ‘Gain-of-Function’ experiments with highly pathogenic viruses such as avian influenza has brought the problem of biological security to the attention of many within but also beyond the life science community. It also has left some of them wondering what biological security is and how it can be incorporated into the life sciences. What steps should be taken to ensure that these and other dual use research activities are not misused?

It is being increasingly recognised that biosecurity and biosafety are not only relevant to activities within a laboratory, but also extend to the effects that these activities can have outside the laboratory if they result in accidental outbreaks of diseases in humans, animals or plants.

The international basis for the prevention of the hostile misuse of life sciences is the Biological and Toxin Weapons Convention which this year, on 26 March 2015, has been in force for forty years. The Convention was the first treaty to prohibit the development and possession of an entire category of weapons. At this moment 173 States Parties have ratified the Convention (and the Convention has a further 9

Signatories). At the Seventh Review Conference of the Biological and Toxin Weapons Convention in 2011, of which I was President, the States Parties agreed on the need for all those engaged in the life sciences to be involved as key stakeholders in the protection of their work from hostile misuse, and therefore on the importance of broad biosecurity education.

This book with its 21 chapters addresses the need for biosecurity education, in six sections on the history of threats and responses; scientists, organisations and biosecurity; biosecurity and law enforcement; states and biosecurity; and biosecurity and active learning. It is a significant and welcome step forward both in its integrated content and the active learning focus in the associated Team Based Learning exercises. I am convinced that this approach will help all those engaged in the life sciences - in government, industry or academia – to become more aware of biosecurity and of their responsibilities for it.

It is therefore a great pleasure to commend the authors and editors for their work and the Governments of Canada, Jordan and the United Kingdom for their funding and involvement in the production of this book under the Global Partnership.

Ambassador Paul van den IJssel

Foreword: The Responsibilities of Scientists

It is an unfortunate fact that some of the advances of science have the potential both to benefit and blight the lives of humanity. It is therefore our collective responsibility, as one human family, to ensure that scientific progress should improve the lives of many and leave us all unharmed in its wake. It was with this in mind that Matthew Meselson, Thomas Dudley Cabot Professor of the Natural Sciences at Harvard University, published a seminal article at the beginning of the 21st Century, as the promise of Biotechnology was dawning on the wider global scientific community. In it he posed questions to life scientists and to all those who had concerns about how this new technology might advance. Under the title of *Averting the Hostile Exploitation of Biotechnology*¹ Meselson asked if "biotechnology, like all major predecessor technologies, will come to be intensively exploited for hostile purposes?"¹

To reinforce this point, Meselson opened the article with a quote from a 1989 prize-winning essay from the US *Naval War College Review*² in which the author, Commander Stephen Rose, noted that:

"The outlook for biological weapons is grimly interesting. Weaponers have only just begun to explore the potential of the biotechnology revolution. It is sobering to realize that far more development lies ahead than behind."²

However, elsewhere in that essay, Rose also suggested that the application of the biotechnology revolution to hostile purposes could be hindered by "the cumulative effect of several interlocking initiatives: economic sanctions, export controls, an augmented defensive capability, and participation in arms control negotiations." This approach has since become known as the "Web of Prevention", in which governments, organisations and individuals – including scientists and scientific organisations – play a role in helping to prevent the hostile application of the fruits of a biotechnology revolution which is fundamentally well-intentioned.

Of course, in recent years we have witnessed great developments in awareness and education for life scientists, particularly with regard to the internal aspects of the Responsible Conduct of Research, such as the ethics of experimentation, proper use of data, and the avoidance of plagiarism. However, there has been considerably less progress in relation to the external aspects, including public communication, advocacy, and dealing with emerging technologies.³ As the revolution in life sciences gains pace, these external aspects of responsible conduct are certain to become ever more important because of its impact on society. It is into this category of concerns that biological security must fall.

In the period since Meselson published his article, we have seen a growing interest in the development of codes of conduct⁴ and oversight systems⁵, designed to help limit the misuse of life sciences. Yet, it has also become clear that life scientists generally have a limited awareness of the risks and issues associated with dual-use research and biosecurity, and that such codes of conduct and oversight systems are unlikely to be successful in the absence of greater understanding. This critical gap in the education of life scientists is not surprising as, unlike the cases of nuclear and chemical security, where the International Atomic Energy Agency and, increasingly, the Organisation for the Prohibition of Chemical Weapons, have taken a lead in improving the security education of nuclear and chemical scientists, there have been few education initiatives in relation to Biological Security.

Thus, a major objective of this book is to provide university life-science lecturers and students with a resource to enhance university biosecurity education around the world. The 21 chapters in the six sections on the history of threats and responses; scientists, organisations and biosecurity; biosecurity and law enforcement; states and biosecurity; and biosecurity and active learning, are built around a central focus on the responsibilities of scientists for biosecurity, and serve to give a proper context for understanding what is at stake in the coming decades. For this reason I warmly welcome the production of *Preventing Biological Threats* and look forward to seeing it, and the associated Team Based Learning exercises, widely used to support an expanding range of university courses here in the Middle East and around the world.

HRH Princess Sumaya bint El Hassan, President of the Royal Scientific Society of Jordan

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²Stephen Rose, 'The Coming Explosion of Silent Weapons', *Naval War College Review*, Summer 1989, reprinted in John N. Moore and Robert F. Turner (eds.) *International Law Studies, Volume 68: Readings in International Law from the Naval War College Review, 1978 – 1994*, US Naval War College, 1995, available at <https://www.usnwc.edu/Research---Gaming/International-Law/New-International-Law-Studies-%28Blue-Book%29-Series/International-Law-Blue-Book-Articles.aspx?Volume=68> (accessed 25 June 2015).

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Chapter 1: Introduction and overview

Simon Whitby and Tatyana Novossiolova

Biosecurity: The Need for a Comprehensive Approach

1. In this Guide we use the term “Biosecurity” to mean successful minimising of the risks that the biological sciences will be deliberately or accidentally misused in a way which causes harm for humans, animals, plants or the environment, including through awareness and understanding of the risks. “Biosecurity” can have a variety of meanings in other specific contexts (see below), but it is a convenient term for the broad range of concepts and activities with which this book is concerned.
2. Biosecurity involves a complex and rapidly evolving set of issues that concern everyone: policy makers, legislators, industry, academia, scientists, science educators, and students, as well as the general public. This guide will enable the reader to understand the issues involved, and to come to a view about risks and responsibilities, and its intention is to guide and inform decisions and actions.
3. Some of the advances of modern biotechnology are ‘dual use’. They may offer both exciting prospects for human betterment, and also serious, and potentially catastrophic, dangers to us all. By promoting human and animal health, and food security, and by responding to environmental challenges, modern biology enriches our lives and contributes to a better future. Yet, there are also concerns, about the possible results of accidents or deliberate misuse.
4. Policies – international, national, and institutional –that aim to prevent the misuse of the life sciences, need to be maintained and strengthened in the coming decades into a comprehensive and integrated web of prevention (see Chapter 7). The objective of this book is to help the reader take a constructive part in that process of ensuring that the life sciences are used only for peaceful purposes.
5. This Guide to biological security issues¹ aims to help the reader appreciate the common goal that all stakeholders share – to ensure a safer world. Consequently, it details how to:

- i. assess, evaluate and make informed judgements about biological benefits and threats and global responses to them;
- ii. evaluate the biosecurity aspects of scientific research and industrial processes, and ensure your own work is responsibly conducted;
- iii. collaborate with others in government, academia or industry to inform and educate your colleagues about biosecurity issues.

6. **Part 1, Threats and Responses**, deals with the potential threats from scientific and technological advances and naturally occurring disease outbreaks alike, and the organisational responses to these. Threats may result from modifications to biological organisms, novel techniques for delivering bioweapons, terrorist attacks, or natural disease outbreaks. Responses to minimise the risks of these emerging threats include international conventions on the prohibition of biological weapons, and the creation of a 'web of prevention'.

7. Chapter 2, by Koos van der Bruggen, addresses the issue of dual-use research: benignly intended life science research that can be reasonably anticipated to provide knowledge, information or technologies that could be directly misapplied to pose a significant threat to public, animal and/or plant health, critical infrastructure or the environment.² He addresses the controversies surrounding the H5N1 bird flu virus and its potential for airborne transmission to mammals.

8. Chapter 3, by Kathryn Nixdorff, details the emergence of beneficial developments in civilian science, and their relevance to the health and well-being of mankind, as well as the application of such developments to military programmes, where States actively promote the use of biology for hostile purposes.

9. Chapter 4 presents an overview of the biosecurity problem in so far as it applies to terrorism. Catherine Jefferson's chapter discusses three notable cases of bioterrorism, and assesses the risks of the emerging phenomenon of the DIY-bio community.

10. Maureen Ellis, in Chapter 5, deals with biosecurity as a global health security issue, where disease is located on a spectrum from deliberately induced, through accidentally caused disease to disease that is naturally occurring. Ellis' chapter

highlights the global consequences of naturally occurring disease outbreaks including a case study of the 2014/2015 West Africa Ebola outbreak.

11. Chapter 6, by Jez Littlewood, focuses on biosecurity from the perspective of prohibition. The Biological and Toxin Weapons Convention (BTWC) prohibits States from the development, production and stockpiling of biological and toxin weapons, and thus bans an entire class of weapons. It does so by requiring that biology is used only for prophylactic, peaceful and protective purposes and thus allows innovation in life and associated sciences to flourish.

12. Graham Pearson's Chapter 7 considers developments in life science, their potential for hostile application, and the regulatory regimes that mitigate the misuse of such developments within the overall context of a 'web' of preventative measures that are integrated, comprehensive, complementary, mutually reinforcing and effective.

13. **Part 2, Scientists, Organisations and Biosecurity**, focuses on the role of life scientists and international and national bodies in the implementation of biosecurity policies and practices. From global prohibition to more local and personal initiatives, this section considers the responsibilities of research communities, industry and international bodies, such as the BTWC Implementation Support Unit, in ensuring biosecurity.

14. Chapter 8, by Gerald Walther, traces the origins and contemporary evolution of the dual-use debate. He considers the range of national and international dual use events and the steadily increasing interest in biosecurity that has led in the US to the establishment of a permanent advisory body to the US government on dual-use issues, the National Science Advisory Board for Biosecurity.

15. Chapter 9, by Ralf Trapp, discusses the concept of a chemical and biological spectrum within the existing chemical and biological weapon prohibition regimes, and considers uncertainties where chemistry and biology converge.

16. Chapter 10, by Jo Husbands and Katie Bowman, focuses on the biosecurity awareness and education work of scientific organisations. It shows how the scientific community has responded to the challenges of ensuring communication between the biosecurity stakeholders identified in Chapter 8. It also considers national and

international biosecurity awareness-raising initiatives intended to overcome the perceived lack of communication amongst and between national security, life science and ethics biosecurity communities.

17. Chapter 11, by Piers Millett, gives an account of the coordinating and communicating functions of the BTWC Implementation Support Unit, which is a vital hub in the overarching web of prevention acting as a channel for coordination and communication, linking various strands of the web of prevention to the prohibition regime.

18. Despite the existence of international treaties, agreements and legal measures to prohibit, minimise and deal with biological threats, as seen in Part 1, such threats nevertheless occur. **Part 3, Law Enforcement and Biosecurity**, considers the role of international and national law enforcement agencies in responding to biosecurity challenges and promoting biosecurity globally. Such organisations as the Federal Bureau of Investigation (FBI) in the US, and INTERPOL, have contingency plans to deal with biosecurity events through intelligence gathering, preventative measures and capacity building and outreach.

19. Chapter 12, by Will So, gives an overview of the contribution of law enforcement to the overarching web of prevention. He addresses the FBI's Biosecurity Program, the scope of their biosecurity mandate, and their work on biosecurity in relation to three case studies, namely 1918 Spanish Flu, poliovirus, and mousepox virus. The chapter illustrates the links between domestic law enforcement and international legally-binding regulatory regimes, and gives examples of ways in which the Bureau's biosecurity outreach work contributes to minimising the risks of misuse.

20. Chapter 13, by Guy Collyer, sets out the role of INTERPOL and discusses its vision, mission and strategic priorities, as well as the legal framework within which it operates. He addresses the relationship that INTERPOL has with international law enforcement agencies on biosecurity in a changing world.

21. The effectiveness of international regulation depends upon participating nation states having effective internal biosecurity provision. **Part 4, States and Biosecurity**, gives insights into government approaches to fostering an effective biosecurity system in one country in Europe – Denmark; one in North America – Canada; one in Africa – South Africa; and one in the Middle East – Jordan.

22. Robert Petersen, in Chapter 14, gives an overview of the biosecurity system introduced by Denmark in 2008, highlighting the origins of Danish biosecurity, the implementation of the system, Danish outreach efforts, attitudes towards biosecurity in Denmark, technology control, research and knowledge, and international cooperation. The chapter illustrates how states, through the enactment of national legislation, can contribute to strengthening the web of preventative measures that are required to mitigate the risk of hostile misuse.

23. In Chapter 15 Jwan Ibbini gives an overview of Jordanian efforts to enhance biosecurity and to organise preparedness. This chapter highlights key Jordanian stakeholders and addresses the development of Jordan's Biosecurity Program. It gives an overview of the National Structure of Biosecurity in Jordan, as well as the efforts of the Hashemite Kingdom to promote a culture of biosecurity.

24. Chapter 16, by Louise Bezuidenhout, addresses South African biological weapons activities during the Apartheid era, followed by post-Apartheid developments and the complex challenges surrounding the evolution, implementation and development of a biosecurity regime in that country. She argues that changes in political culture and corresponding changes in political will can, over a short number of years, contribute to improved biosecurity; but she warns that, in spite of demonstrable progress, efforts must continue to foster a biosecurity culture amongst a broad range of stakeholders, so as to reinforce biosecurity in modern South Africa.

25. Continuing the theme of state biosecurity initiatives, Kirsten Almquist, Julia Fernandez, Stacey Mantha, and Morgan Kafenzakis elaborate in Chapter 17 on Canada's biosecurity initiatives, which have approached the biosecurity problem from a focus on human pathogens and toxins. This chapter gives an overview of the history and evolution of human pathogen and toxin oversight, as well as the extent to which biosecurity in this area in Canada is underpinned by legislation and regulation.

26. Chapter 18, by Catherine Rhodes, gives an overview of the development and evolution of international governance as it relates to biosecurity. The chapter also describes the relationship between, as well as the impact upon, individual scientists of a broad range of international biosecurity regulations, and the ways in which governance can influence science and science practice. The chapter gives illustrations of the relevance of specific biosecurity regulations to science, including the prohibition regimes related to biological and chemical warfare, biorisk management, disease control and the protection of biodiversity.

27. **Part 5, Biosecurity and Active Learning**, is aimed primarily at educators planning to implement biosecurity education as part of their curriculum. The complex and interdisciplinary nature of the subject presents particular challenges within conventional, predominantly subject-based approaches to curriculum planning. Active learning methods have proved to be effective in educating students from a variety of backgrounds in biosecurity issues.

28. Chapter 19, by Lida Anestidou and Jay Labov, gives an overview of active learning approaches and explains how they differ from traditional lecture-based approaches to teaching. Through case studies and a variety of examples, the authors seek to highlight the added value of aligning assessment methods with the overall course goals and objectives. The chapter further explores the concept of ‘backward design’ and its relevance to enhancing the effectiveness of training programmes.

29. Chapter 20, by Tatyana Novosiolova, elaborates on the benefits of the active learning and teaching methodology, Team Based Learning. In this chapter, Novosiolova gives an account of a proof of concept seminar that was held in 2012, which brought together students from a range of life science and social science disciplines.

30. Finally, in **Part 6, Conclusions**, we show the importance of strengthening biosecurity and building the web of prevention into the future.

31. Appendix A contains information about additional educational resources in biological security, relevant policy documents, guidelines, and related publications.

32. As in many complex fields of knowledge, the use of terminology can be variable. The term ‘biosecurity’ has a number of different definitions, as illustrated in Table 1.1. In this Guide we use the term in the broad sense explained in Paragraph 1 of the chapter.

Table 1.1: Definitions of ‘Biosecurity’

Source	Definition of Biosecurity
World Health Organisation (WHO), ‘Laboratory Biosafety Manual: Third Edition’, 2004 ³	“Laboratory Biosecurity refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.”
WHO, ‘Biorisk Management: Laboratory Biosecurity Guidance’, 2006 ⁴	“Laboratory biosecurity describes 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.”
Food and Agriculture Organisation of the United Nations (FAO)	“Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. Biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their

	<p>products, and the introduction and management of invasive alien species and genotypes. Biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.”⁵</p>
<p>FAO, World Organisation for Animal Health (OIE), and the World Bank, ‘Biosecurity for Highly Pathogenic Avian Influenza’, 2008⁶</p>	<p>Biosecurity refers to the “implementation of practices that create barriers in order to reduce the risk of the introduction and spread of disease agents. The three principle elements of biosecurity are:</p> <ol style="list-style-type: none"> 1) <u>Segregation</u> The creation and maintenance of barriers to limit the potential opportunities for infected animals and contaminated materials to enter an uninfected site. This step, properly applied, will prevent most infection. 2) <u>Cleaning</u> Materials (e.g. vehicles, equipment) that have to enter (or leave) a site must be thoroughly cleaned to remove visible dirt. This will reduce the risk from a contaminant (organism). 3) <u>Disinfection</u> Properly applied, disinfection will inactivate any contaminant that is present on materials that have already been thoroughly cleaned.”

References

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²For a full definition and further information on Dual-Use Research of Concern as defined by the US Government, see <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern> (accessed 13/11/2015).

³Available at http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/ (accessed 27/07/2015).

⁴ Available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/ (accessed 27/07/2015).

⁵ See <http://www.fao.org/biosecurity/> (accessed 27/07/2015).

⁶ See <http://www.oie.int/doc/ged/D5896.PDF> (accessed 27/07/2015).

Chapter 2: Biosecurity challenges in the 21st century: the case of gain-of-function experiments

Koos van der Bruggen

Key learning objectives

- i. Understand the meaning and impact of the concept of dual use research;
- ii. See and understand how this concept of dual use research is applied in a concrete case;
- iii. Get insight into and understand the ethical, legal and social responsibilities of scientists;
- iv. Get to know different and divergent arguments as well as the interests of involved parties (scientists, government, citizens).

Introduction

1. In September 2011, Rotterdam-based virologist Ron Fouchier announced his research group's finding that the H5N1 (bird flu) virus has the potential to gain airborne transmissibility between mammals. Fouchier submitted the research results of his gain-of-function study to Science for publication. At approximately the same time, US-based virologist Yoshihiro Kawaoka (Japan) submitted similar research results to Nature. For reasons of biosecurity the editorial boards of both journals decided to ask the body that had funded the two studies – the US National Institutes of Health (NIH) – to review the manuscripts. This marks the beginning of what has been called the gain-of-function debate. These gain-of-function experiments have developed into some of the most controversial experiments in the life sciences. This chapter will deal with the issues that are at stake in the controversy about gain-of-function research. An overview of the main debates and key positions will be given. First, a concise description of the concept of gain-of-function research will be

given, as well as a summary of the lessons that are being, or should be, learned from this debate. The chapter then allows the reader to develop a critical appreciation of the history and evolution of this contemporary biosecurity problem through an in-depth explanation of the case of gain of function. A section focusing on analysis and evaluation from a biosecurity perspective brings the chapter to a conclusion.

Gain-of-function research

2. It makes sense to observe that the concept of gain-of-function was not used from the very start of the H5N1 debate to discuss the pros and cons of the experiments. It was first used in the concluding March 2012 report of the US National Science Advisory Board for Biosecurity to refer to possible further experiments of the same kind: “The Board also noted the need for guidelines to aid in the determination of how/whether certain types of “gain-of-function” experiments with influenza should be conducted or communicated.” This was because “further gain-of-function experiments of this type are likely to be contemplated by these and other laboratories around the world. Experiments that change the mode of transmission or host range of a zoonotic agent are of particular concern and require detailed analyses of risks and benefits before they are conducted or communicated.”¹ Following this recommendation, the US Department of Health and Human Services published a framework to judge this kind of research. In this framework the concept of gain-of function is explicitly stated: “One of the goals of HPAI H5N1 research is to identify the genetic changes that correlate with transmission or enhanced virulence of these viruses in mammals. For the purposes of this paper, studies that enhance these biological properties are referred to as “gain-of-function” research”. In a footnote it is explained that “Gain-of-function” is typically defined more broadly as a mutation that confers a new or enhanced activity to a protein. For the purposes of this paper, “gain-of-function” studies refer specifically to those that increase the transmissibility, increase the pathogenicity, or alter the host range of HPAI H5N1 viruses”.² Gain-of-function is not a new concept. Gain-of-function experiments in a general sense have become daily practice in the modern life sciences. As Lipsitch and Galvani state: “Gain-of-function is a common and important approach in biological experimentation, and is not by itself cause for concern.”³ Gain-of-function

experiments are experiments in which new properties are added to biological agents such as viruses. The reverse – loss of function - is also possible: properties are taken away from biological agents. Although, according to Lipsitch and Galvani, gain-of-function by itself is not a cause of concern, it is noteworthy that the so called experiments of concern that were described already in the US National Research Council's Fink Committee Report of 2004 are in fact examples of gain or loss of function (see Box 2.1).⁴

Box 2.1: Experiments of concern.

Experiments of concern are experiments that:

- i. Would demonstrate how to render a vaccine ineffective;
- ii. Would enhance resistance to therapeutically usefully antibiotic / render a vaccine ineffective;
- iii. Would enhance virulence of a pathogen or render a non-pathogen virulent;
- iv. Would increase the transmissibility of a pathogen;
- v. Would alter the host range of a pathogen;
- vi. Would enable the evasion of diagnostic / detection modalities;
- vii. Would enable the weaponisation of a biological agent or toxin.

Lessons to be learned

3. The awareness among life scientists of the possible misuse of the results of their research is limited.

Since the anthrax letters incident of 2001 many activities have been undertaken to make scientists more aware of the possible misuse of their research. Educational programmes have been developed, codes of conducts implemented, regulations strengthened, conferences organised, practical guides issued, biosecurity officers appointed and numerous other measures undertaken with the intention of enhancing the 'web of prevention'. And certainly significant results have been reached. However, a lot still has to be done. To give one example: in most universities biosecurity is not a part of the education courses for life scientists. As long as that is the case, it is primarily by 'incidents' as the H5N1 debate that researchers are

confronted with biosecurity and dual use questions. More efforts are necessary to make and to keep the community of life scientists aware of biosecurity.

4. Ethical, legal and social responsibilities of scientists.

The issue of awareness is closely linked to the broader issue of the ethical, social and legal responsibilities of scientists (see Chapter 9). This responsibility also extends to (bio)security issues, and could even lead to the question of whether there are any experiments that should not be conducted, as was argued by David Relman.⁵ The gain-of-function debate shows that calls – such as by the American Association for the Advancement of Science (AAAS) – for more attention to these issues in the education of researchers and scientists are justified and necessary.⁶ And the US National Academies state: “Scientists have additional responsibilities to society. Even scientists conducting the most fundamental research need to be aware that their work can ultimately have a great impact on society... science and technology have become such integral parts of society that scientists can no longer isolate themselves from societal concerns”.⁷ As was stressed in a debate organized by the Royal Netherlands Academy of Arts and Sciences (KNAW), this responsibility can be strengthened by ethical review boards and codes of conduct.⁸ However, it should be realised that taking such a responsible approach does not automatically lead to consensus among scientists on specific research projects, such as the H5N1 case. It is beyond dispute that researchers such as Kawaoka and Fouchier were aware of the risks of their projects. Indeed, Fouchier had been a member of the advisory board on Biosecurity of KNAW.

5. Gap of distrust between life scientists and security experts.

Several debates in the past few years have shown that there is a kind of distrust among life scientists toward security experts, who suddenly entered into the life sciences theatre. The most common reproaches are that these security experts lack even the most basic knowledge of life science, that they underestimate the benefits of the research, and overestimate the security threats. The other way around, security experts are afraid that scientists neglect even the most basic security measures and that they underestimate or do not even see the security risks. Both parties should learn that building trust between the scientific and the security community is an important condition for dealing with biosecurity and dual use issues.

6. International character of the biosecurity and dual use problem.

Research in the life sciences is almost by definition international research. Projects take place all over the world, researchers work all over the world; there is cooperation all over the world between universities and research institutes. Last but not least, research results are spread worldwide via journals and the Internet. This means that the risks of misuse of the research results are not limited to the direct surroundings of the location where the research takes place. This calls for international cooperation. The events of the H5N1 debate have shown that international cooperation is at best on an ad hoc basis. Many such arrangements had to be developed and approved during the ongoing debates.

7. Lack of clarity of biosecurity regulations.

Even given recent efforts to provide more clarity, governments often cannot convince scientists whether and why their research should be classified as dual use. This lack of clarity is exacerbated by the difference in regulations and applications between states. Life scientists already have to deal with many different rules, laws and obligations, e.g. in the field of environment, biosafety, academic culture, bioethics etc. etc. They are not very eager to adopt a new set of rules regarding a risk that most of them do not perceive as such, because - as noted before - security issues are not seen by most scientists as their business. The lack of clarity - and sometimes differences between states - makes this reluctance greater. Lesson to be learned: governments should develop regulations that are clear and not prone to misunderstandings. Moreover, the rules should be comprehensible and acceptable for the scientific community.

8. Institutional organisation of biosecurity regulation.

The gain-of-function debate has shown that one of the consequences of this difference in perspectives is that it is difficult to identify the 'problem owner' of biosecurity issues. On the national level, involved Government departments discuss with each other the question of what department is or is not responsible for existing or still to be developed biosecurity regulations. It depends on the chosen emphasis (science, public health, security, safety), which department takes the lead. The consequence could be (and sometimes is) fragmented and thus unclear regulations. More or less the same happens at the international level. The WHO was the first international organisation that organised a special meeting on the H5N1 case (February 2012). One of the

criticisms was that predominantly influenza experts had been invited. One year later, in a second conference on this issue, security experts were invited also. The gain-of-function debate has been given attention in the meetings of the BTWC but, given the character of these meetings, this did not lead to any decisions, let alone regulations. Moreover, it could be observed that the main contributions were given in side events by organisations or scientists that were already involved in the gain-of-function debate.

Gain-of-function debate: what happened?

9. Why was it that the experiments by Fouchier and Kawaoka prompted such enormous debates? Looking back at the start of the debate (see Box 2.2) it is remarkable that Fouchier announced his research group's finding (see Box 2.3) as being the result of what he himself termed a 'stupid experiment'.⁹ He submitted the research results to Science. At approximately the same time, Yoshihiro Kawaoka (Japan) submitted similar research results to Nature. The editorial boards of both journals decided to ask the US National Institutes of Health (NIH), which had funded both studies, to review the manuscripts. They did so in line with agreements between researchers, science journals and government officials in the United States (and elsewhere) regarding manuscripts whose content could be regarded as dual use: the knowledge or technologies acquired through scientific research that could possibly be misused for criminal or terrorist purposes or for military reasons. The NIH asked the US National Science Advisory Board for Biosecurity (NSABB) to screen both papers on biosecurity risks.¹⁰ In December 2011, NIH released a statement with the recommendation that: "Due to the importance of the findings to the public health and research communities, the NSABB advised that the general conclusions highlighting the novel outcome be published, but that the manuscripts should not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm".¹¹ The NSABB also recommended that language be added to the manuscripts to better explain the goals and potential public health benefits of the research, and to detail the extensive safety and security measures taken to protect laboratory workers and the public. The US Department of Health and Human Services (HHS) agreed with this assessment and passed these non-binding

recommendations to the authors and journal editors. When the recommendations were announced, they sparked off a heated debate among scientists, politicians and the media. It was the first time that publication (in full) of a scientific article had been advised against for dual use and biosecurity reasons.

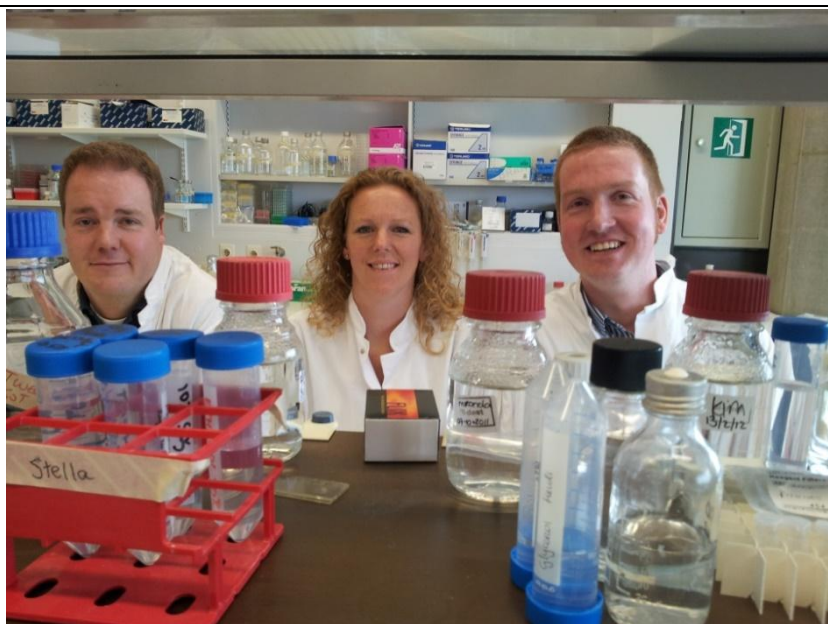
Box 2.2: Timeline of the gain-of-function debate.

2011, September	At a European Influenza conference on Malta, Rotterdam-based virologist Ron Fouchier announced his research group's finding that the H5N1 virus has the potential to gain airborne transmissibility between mammals.
2011, Autumn	Submission to <u>Science</u> and <u>Nature</u> by Fouchier (Rotterdam) and Kawaoka (Madison) of publications on mammalian transmissibility of an H5N1 avian influenza strain; both articles are sent for review to the National Science Advisory Board for Biosecurity (NSABB)
2011, December 20 th	NSABB recommends that the papers be published without certain details on the experimental design. ¹²
2012 January 20 th	Influenza researchers call for a temporary moratorium on research involving H5N1 that might lead to the creation of highly pathogenic and highly transmissible strains. ¹³
2012, February	WHO convenes a meeting of public health and influenza experts to discuss the manuscripts. The WHO recommends that the manuscripts be published in full, after biosecurity and communication issues have been addressed. ¹⁴
2012, March -April	The NSABB reconsiders the revised manuscripts and votes in favour of the publication. The vote in favour of the Kawaoka paper was unanimous, that in favour of Fouchier was split. ¹⁵
2012, April	The Government of The Netherlands grants an export license to

	publish the Fouchier manuscript in <u>Science</u> .
2012, June	Publication of both papers. ¹⁶
2013, February 21 st	The Department of Health and Human Services (US) releases a framework for guiding Funding Decisions about research proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 viruses that are transmissible among mammals by respiratory droplets. ¹⁷
2013, February 22 nd	Draft policy on “United States Policy for Institutional Oversight on Life Sciences Dual Use Research of Concern” is released for public comment.
2013, February 26-28 th	Meeting on “Dual Use Research of Concern: Current Issues and Innovative Solutions”. WHO, Geneva, Switzerland.
2013, September	Dutch court states that the Dutch Government was right in asking for an export license for publishing Fouchier’s article. Erasmus Medical Center appeals.
2013, October 16 th	Letter of Prof. Giorgio Palù (European Society for Virology) to Jose Manuel Barroso, President of the European Commission, stating ESV’s support for the research performed by Fouchier. ¹⁸
2013, November	Publication of advisory report on dual use research by Royal Netherlands Academy of Arts and Sciences. ¹⁹
2013, December 18 th	Letter of Dr Wain-Hobson on behalf of the Foundation of Vaccine Research to Jose Manuel Barroso, in response to the letter of ESV and proposing to organise a scientific briefing for the European Commission on gain-of-function research. ²⁰

2014, June 25 th	Royal Netherlands Academy of Arts and Sciences organises a debate on gain-of-function research between Giorgio Palù and Simon Wain-Hobson. ²¹
2014, June-July	Incidents with highly pathogenic microbes in federal laboratories: accidental shipment of live anthrax, discovery of forgotten live smallpox samples, shipment of a dangerous influenza strain.
2014, September 24 th	Release of the “United States Government Policy for Institutional Oversight on Life Sciences Dual Use Research of Concern”. ²²
2014, October 17 th	The White House Office of Science and Technology Policy announces a “pause” that suspends new grants for gain-of-function research involving influenza, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).
2014, December 15 th - 16 th	Symposium on “Risks and Benefits of Gain-of-Function Research”, organised by the National Academies of Sciences, Washington DC.
2015 May 5 th	NSABB Meeting on Framework for Conducting Risk and Benefit Assessments of Gain-of-Function Research.
2015, September 28	NSABB Meeting on Progress of Gain of Function Debate
2015, October 19	Publication of Government Reaction on advisory report on dual use research by Royal Netherlands Academy of Arts and Sciences. ²³
2015, October 21	Presentation of Report by European Academies Science Advisory Council on Gain of Function Research ²⁴

Box 2.3: Young scientists who did the job.²⁵



Yoshihiro Kawaoka and Ron Fouchier rarely set foot in the high security labs where the experimental work on their two highly controversial H5N1 studies was done. That work was carried out by younger researchers who have remained invisible during the debate. Yet for them, the stakes were just as high — higher, perhaps, because a paper in Science or Nature can be a critical career booster. While Fouchier gave interviews, travelled to meetings, and lobbied to get his paper published, first author Sander Herfst stayed in the background, as did Ph.D. students Eefje Schrauwen and Martin Linster, the second and third authors, respectively.

For these researchers at Erasmus MC, the story began in late June 2011, when a test suggested that a ferret housed in a cage adjacent to an infected one had traces of the H5N1 virus in its airways. “We were very excited,” Herfst says. “When we showed it to Ron, he just said: ‘Calm down, and do it again. It may be an error.’” It wasn’t. But while he expected to make headlines, Herfst says he never imagined that the paper would get a red light from the NSABB and become the focus of a heated international debate about the limits of academic freedom. Watching the flood of news coverage, “it was strange to think that we had created all of that in our lab,” says Schrauwen. A friend, who had read the news stories but didn’t know that Herfst was involved, warned him to watch out “because they are doing some pretty dangerous things at Erasmus.” Others asked critical questions: “Was this study really necessary?” Linster

says he could usually convince them. “Debates about animal experiments are more difficult.”

Photo and excerpts from a story by Martin Enserink in Science, 22 June 2012, reprinted with permission from the author.

10. In March 2012, the NSABB advised that amended versions of the two papers could be published in full. Following the NSABB’s decision, Nature published Kawaoka’s manuscript.²⁶ Fouchier’s paper remained unpublished, however, because he was required to apply for an export licence for the manuscript under the terms of the national Strategic Goods Decree in The Netherlands.²⁷ However, this was surprising for many researchers: the Regulation makes an exception for basic scientific research, and had never before been applied to scientific manuscripts in the life sciences. Fouchier’s employer, Erasmus Medical Centre in Rotterdam, decided to apply for the licence under protest. The licence was issued at the end of April, allowing the manuscript to be published in Science.²⁸ This was not the end of the debate. The Erasmus Medical Centre filed an objection to the compulsory licence. The Dutch Minister for Foreign Trade and Development Cooperation disallowed the objection in December 2012. The case was then submitted to a District Court, that ruled on 20 September 2013. It rejected the claim of Erasmus Medical Center by considering that non-proliferation was a priority in the Regulation and that exemptions from the licence obligation (for example for reasons of basic scientific research) should be narrowly interpreted. In addition, the Court stated that this particular case did not involve basic scientific research, because it had a practical purpose (demonstrating the airborne transmissibility of the H5N1 virus). The Erasmus Medical Centre issued an appeal to a higher court, which is still pending at the time of writing.

11. The decision of NSABB was not the end of the gain-of-function debate. One of the issues was the discontent in scientific circles with the use of the broader concept of gain-of-function for these specific applications in influenza research. During a meeting at the Royal Society in London (December 2013) it was said that the term ‘gain-of-function’ is not appropriate and potentially misleading. Other possible terms

were discussed, including ‘experimental modification of microbes’ and ‘microbial manipulation in transmission research’. Furthermore, there was a plea for greater discussion and debate within the community of experts on the risks of experiments, as well as substantial efforts to raise awareness. Important was the observation that influenza is only one field which must deal with these issues: other viruses, bacteria and parasites are also subject to concerns.²⁹ There were more debates: in the autumn of 2013, both supporters and opponents of gain-of-function research approached the European Commission with open letters. The European Society for Virology (ESV) made a strong case in favour, while the Foundation for Vaccine Research (FVR) in response brought up a list of objections.³⁰ The Netherlands Royal Academy of Arts and Sciences organised a debate on gain-of function in June 2014. The first signatories of the ESV-letter (Giorgio Palù) and the FVR letter (Simon Wain-Hobson) had a discussion with each other on the pros and cons of gain-of-function research. It was emphasised that all researchers (for or against gain-of function) are devoted and driven people trying to solve important problems. There was a strong plea for an open discussion on these kinds of issues, not only within science, but also between scientists and the public. In this debate it became clear that the individual responsibility of scientists will not cease to be an important aspect for dealing with gain-of-function research. This responsibility can be strengthened by ethical review boards and codes of conduct. However, as standards need to be defined and as self-regulation may fail, regulation will always be necessary.³¹

12. The gain-of-function debate became intensified after the summer of 2014, when the US Government decided to suspend all federally funded planned and current gain-of-function studies in the field of influenza, SARS and MERS. This period of suspension is meant “to launch a deliberative process to assess the potential risks and benefits associated with a subset of life sciences research known as “gain-of-function” studies. With an ultimate goal of better understanding disease pathways, gain-of-function studies aim to increase the ability of infectious agents to cause disease by enhancing its pathogenicity or by increasing its transmissibility”.³² Incidents in major American laboratories— although with other pathogens – may also have given the White House cause to take these rigorous measures. The National Research Council (NRC) of the National Academies of Sciences had been commissioned to organise a scientific debate on the benefits and risks of gain-of-function studies. The NSABB

would serve as the official Federal advisory body for providing advice on oversight of this area of dual-use research. Informed by discussion at the NRC public consultations, the NSABB would provide recommendations that will be the basis for the development and adoption of a new US Government policy regarding gain-of-function research. A first discussion took place on 15 and 16 December 2014.³³ All key players—both for and against—were present. Many relevant issues were treated, such as scientific interest, benefits and risks, and safety. One of the issues of debate here was again on terminology. Earlier doubts about whether it was wise to use the concept of gain-of-function to describe the ‘experiments of concern’ were repeated here. In that context it was noteworthy that a relatively large number of the scientists present were pleading for the resumption of the gain-of-function studies, especially for MERS and SARS. Another observation is that biosecurity issues got relatively little attention in the debates (see Box 2.4 for an alternative view). It seems that the debate had shifted to scientific and biosafety arguments for and against such research. Questions on the possible dual use of this research were not very prominent in this debate, and neither in a similar debate in Hannover.³⁴ This is important because the gain-of-function debate started with questions on the possible dual use of these research experiments.

Box 2.4: Biosecurity expert and commentator: David A. Relman.



David A. Relman, M.D., is the Thomas C. and Joan M. Merigan Professor in the Departments of Medicine, and of Microbiology and Immunology at Stanford University, and chief of infectious diseases at the Veterans Affairs Palo Alto Health Care System in Palo Alto, California. He is also co-director of the Center for International Security and Cooperation and senior fellow at the Freeman Spogli Institute for International Studies at Stanford University.

Dr. Relman's primary research focus is the human indigenous microbiota (microbiome), and in particular, the nature and mechanisms of variation in patterns of microbial diversity and function within the human body, and the basis of microbial community resilience.

He has become one of the most prominent participants in the gain-of-function debate. He is very critical about the Fouchier and Kawaoka experiments. This can be illustrated with his contribution to a Hastings Centre Report:

"We should also remember that research funders often issue calls for research proposals and write contracts that address requests for specified products. An example is the National Institutes of Health-sponsored Centers of Excellence in Influenza Research contract with Erasmus University that funded the deliberate construction of a highly pathogenic strain of avian influenza virus with enhanced transmissibility among mammals.

"What kinds of conclusions are enabled by these considerations of uncertainty? First, certain kinds of experiments may have predictable outcomes that demand special scrutiny before they are undertaken and may deserve to be declared unethical and morally forbidden. For example, experiments that are designed and likely to yield novel biological agents with high degrees of transmissibility and high levels of virulence or resistance to all available countermeasures may incur highly consequential risks for much of the world's population. Typically, too, there are substantial delays before the benefits might be realized. The undertaking of experiments with high potential for significant harm to large populations and limited or much-delayed benefit threatens to violate fundamental principles of justice. The recent announcement by the U.S. Government of a funding pause for certain gain-of-function studies on three pathogenic respiratory viruses, and of a more deliberative process for risk-benefit assessments, is a welcome step in focusing serious attention on these issues."³⁵

Analysis and evaluation from a biosecurity perspective

13. The shift of the gain-of-function discussion from biosecurity to a debate on questions on the nature and usefulness of these experiments can be illustrated by the US Government decision of 17 October 2014. Though biosecurity and biosafety risks are mentioned, the emphasis is on “the context of recent US biosafety incidents and to keep pace with new technological developments, in order to determine which types of studies should go forward and under what conditions”.³⁶ The shift to biosafety and more scientific arguments means that the debate more and more deals with questions such as: What knowledge is gained with these experiments? Could this knowledge be gained in other ways? Can these experiments be done in safe conditions? What is the expected health benefit? How dangerous are the results? Why study a mutant H5N1 virus that does not even occur in nature?

14. One reason for this shift may be that the use of the concept “gain-of-function” for the disputed experiments has been too broad and unspecified. As noted above, gain-of-function research refers to many experiments in present day life sciences. Most of these experiments do not have any biosecurity risks at all. Because of that it is understandable that life scientists are looking for scientific arguments to defend their research. But this shift seems also welcomed by the scientists who perform the disputed experiments, because it relocates the debate to a field (science, biosafety) where they are the experts and where they can argue using their professional expertise. Here the debate revolves around claims that the research results are in the shorter or longer term beneficial to science and to human and animal health, while opponents state that the studies are of no use to society and even dangerous. It is beyond dispute that these are very important issues that need to be dealt with. However, these questions are not directly biosecurity-related. Paradoxically, it is doubtful that this debate on scientific and biosafety issues would have taken place if it had not been initiated by the biosecurity debate on both H5N1 experiments.

15. The shift to biosafety and scientific arguments in the debate should not imply that biosecurity is seen as less relevant. If the political and social context is one of the factors in determining the dual use character of a biological agent or an experiment –

as it is proposed in the Report of the Royal Netherlands Academy of Arts and Sciences³⁷ – it can be easily observed that this context has not changed dramatically since the start of the H5N1 debate in 2011. Security experts could even defend the view that the threat level for a terrorist attack is now greater than a few years ago. Of course, it should also be acknowledged that the threat of a deliberate biological attack is a minor one within the broader spectrum of possible threats.

16. Nevertheless it is important to pay attention to such questions as: what is the likelihood of the experiments being misused, for example by terrorists? How realistic is the risk that terrorists or others will want to misuse the research results and can actually do so? Is it always necessary or even desirable to make the results available to all? The problem is of course that it is very difficult to answer these and comparable questions, even for security experts. This fact can lead to two more or less opposite reactions. Many life scientists are inclined to play down or deny the possible misuse of their research. And on the other hand there are security experts who reason from worst case scenarios. Neither approach is the right way to deal with biosecurity.

17. This observation leads to the question: what should be done? And that brings us back to the lessons learned that already have been presented above. In summary, the need for:

- i. Raising awareness among life scientists of the possible misuse of their research;
- ii. More attention for the ethical, legal and social responsibilities of scientists;
- iii. Bridging the gap of distrust between life scientists and security experts;
- iv. More attention for the international character of biosecurity and dual use research;
- v. Improving clarity of biosecurity regulations;
- vi. Improving the institutional organisation of biosecurity regulation.

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⁷ On being a Scientist: Responsible Conduct in Research , US National Academies, National Academies Press, 1995, (2nd Edition), http://www.nap.edu/openbook.php?record_id=4917&page=20 , p. 20-21

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¹⁰ By asking for a biosecurity review the editorial boards were following a policy procedure established in 2003 by various key life science journals: “(...) there is information that, although we cannot now capture it with lists or definitions, presents enough risk of use by terrorists that it should not be published. How and by what processes it might be identified will continue to challenge us (...)” Journal Editors and Authors Group, *Statement on Scientific Publication and Security*, 15 February 2003.

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¹⁹ Royal Netherlands Academy of Arts and Sciences, *Improving Biosecurity. Assessment of Dual-Use Research Amsterdam*, Royal Netherlands Academy of Arts and Sciences (KNAW), 2013. The report states that the public should be able to trust researchers and others involved to assess whether their results can be misused. The responsibility for making that assessment lies primarily with researchers and other parties in the knowledge chain. However, as most of them are no security experts, they should have the opportunity to request for advice on potential bio-security aspects of their research proposal or research results. This ability to advise on research with potential dual-use aspects requires knowledge and expertise in multiple areas (the science involved, laboratory security, and national and international threat analyses). The KNAW Committee therefore proposed establishing a specialized Advisory Committee: the Biosecurity Advisory Committee for Research in the Life Sciences.

²⁰ ‘Response to the Letter of the European Society for Virology on “Gain-of-Function” Influenza Research and Proposal to Organise a Scientific Briefing for The European Commission & the Conduct a Comprehensive Risk-Benefit Assessment’, http://news.sciencemag.org/sites/default/files/media/Letter%20to%20Barroso_0.pdf (accessed 22 March 2015).

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²² [http://www.phe.govv/s3/dual use/documents/durc-policy.pdf](http://www.phe.govv/s3/dual%20use/documents/durc-policy.pdf)

²³ <https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/kamerstukken/2015/10/19/kamerbrief-met-reactie-op-advies-bouwen-aan-biosecurity/kamerbrief-met-reactie-op-advies-bouwen-aan-biosecurity.pdf>. The main issue in the reaction on the advisory report was that the government did not follow the advice to establish a Biosecurity Advisory Committee for Research in the Life Sciences. Existing institutions should be able to handle relevant questions.

²⁴ EASAC, *Gain of function: Experimental Applications Relating to Potentially Pandemic Pathogens*. EASAC Policy Report 27. Brussels (October 2015)

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Chapter 3: Advances in science and technology, and the evolution of bioweapons capability

Kathryn Nixdorff

Key learning objectives

- i. Understand that while progress in the life sciences over time has greatly benefitted the health and well-being of mankind, these developments have also been used for hostile purposes, starting with the beginnings of advances in microbiology;
- ii. Be aware of the clear evidence that even the most sophisticated advances in biotechnology were applied for the development of a massive offensive biological weapons programme;
- iii. Gain an appreciation for the difficulty in distinguishing offensive and defensive biological weapons work.

Introduction

1. Advances in science and technology over the years have enabled new and improved approaches to countering disease and promoting health in general. This progress in the life sciences is absolutely essential. While we should never lose sight of the enormous benefits to humanity that these developments provide, the warning from Mathew Meselson (Box 3.1) about how every major technology has eventually been exploited for hostile purposes and his question of “must this happen with biotechnology?”¹ is more valid than ever. There have been many stories told about the use of biological warfare as early as in antiquity and the Middle Ages. However, such accounts cannot be viewed as describing dedicated attempts at biological warfare, as there was little understanding of the mechanisms underlying the phenomenon of contagion in those times, or that the illness had any connection with a particular causative agent. This chapter traces some major developments in biology throughout the 20th century and describes how these advances were put to use in offensive biological warfare

programmes. It examines only the programmes pursued by states. Programmes of non-state actors are dealt with in other chapters, particularly in Chapter 4. First, the chapter allows the reader to develop an appreciation of developments leading to the establishment of microbiology as a science, and of developments in microbiology and the subsequent emergence in military programmes of 'traditional' bacteriological agents, as well as their assimilation and incorporation into biological weapons programmes. Second, the chapter organises scientific developments into historic generations of increasing scientific and technological sophistication, and turns to consider second and third generation biological agents. Third, advanced life sciences technologies of relevance to biological warfare are addressed. And fourth, a biological warfare case study of the former USSR is presented, followed by concluding remarks.

Box 3.1: Matthew Meselson.



Photo: Dr. S. Chan,
DNA
Learning Centre

Matthew Meselson is a renowned chemist and molecular biologist at Harvard University. His achievements can best be summed up by the short but very apt quotation upon the occasion of his receiving the Albert Lasker Award for Special Achievement in Medical Science. The dedication read: “The 2004 Albert Lasker Award for Special Achievement in Medical Science honours a researcher who has made world-class contributions to two different aspects of the scientific enterprise: molecular biology and public policy. Matthew Meselson has deciphered fundamental biological problems and has helped to prevent the manufacture and spread of biological and chemical weapons.”² For more details of his achievements see ³.

Early developments leading to the establishment of microbiology as a science: development of traditional bacteriological agents⁴

2. The relationship of specific microorganisms to specific diseases was first recognised towards the end of the 19th century, as a result of developments stemming from two different lines of investigation: studies in fermentation and in medicine.

3. The theory of spontaneous generation remained a viable concept throughout the 18th century and into the 19th century, and it remained for Louis Pasteur (1822-1895) to perform the crucial experiments in the early 1860s that would disprove the theory once and for all, demonstrating in the process that living microorganisms were responsible for the chemical changes that occur during fermentation. These studies represent the beginning of the science of microbiology.

4. Speculation about infectious diseases and contagion began in 1546 with Girolamo Fracastoro, a physician, poet and philosopher of the Renaissance, who reasoned that certain diseases were caused by the passage from one individual to another of what he called “germs”. He also related specific symptoms to specific infectious diseases.

5. Around the same time that Pasteur was disproving the theory of spontaneous generation, Robert Koch (1843-1910), a German country physician, developed a method of isolation of pure cultures of microorganisms on solid culture media which is still used today. He showed that the endospores of the anthrax bacillus (*Bacillus anthracis*) isolated from pure culture could infect animals and cause the disease anthrax, demonstrating that specific microorganisms cause specific diseases. This was the basis of Koch’s famous postulates.

6. The discovery of viruses can be attributed to Friedrich Loeffler and Paul Frosch, studying the foot and mouth disease virus⁵ and Martinus Beijerinck, a Dutch soil microbiologist studying tobacco mosaic disease⁶, both around 1898. Walter Reed, a US army physician, and his medical team in Cuba discovered the first human virus around 1901, the filterable agent causing yellow fever.⁷ Enrique Paschen, a German pathologist, is accredited with the first description of the smallpox virus in 1906.⁸

7. With the recognition of bacteria and viruses as the causative agents of infectious disease, rapid advances were made towards the end of the 19th and the first part of the 20th centuries. Most significantly, scientists began to discover some of the principles of pathogenicity or the factors of infectious agents that actually cause disease, as well as their methods of action. In the context of these studies, the science of immunology began to emerge. These advances had their beginnings in the laboratory of Emil von Behring, working together with Shibasaburo Kitasato on diphtheria and tetanus in 1890. Their work⁹ marked the discovery of toxins as pathogenic factors of microorganisms, and of antibodies as crucial elements of the immune system.

Application of the developments in microbiology to biological warfare in World War I

8. It is significant that the first countries to apply the new knowledge gained about bacterial infections to investigate the potential of using specific biological agents as weapons were Germany and France, whose scientists had contributed most to the establishment of microbiology as a science towards the end of the 19th century.¹⁰ In World War I, cavalry and draught animals were of crucial tactical importance. German sabotage operations employed the use of biological agents such as the bacteria Bacillus anthracis (causative agent of anthrax) and Pseudomonas mallei (causative agent of glanders) to damage horses and livestock. No bacterial warfare was waged against humans by Germany. France apparently also had a similar biological sabotage programme directed against German livestock.¹¹

9. The 1899 Hague Declaration¹² (Annex, Section II, chapter 1, Article 23), which is part of the 1899 Hague Convention, officially banned the use of poisons and poisoned arms. Prior to the 20th century, chemical, biological and toxin weapons were lumped together under the category of poisonous weapons, so that this treaty made biological warfare clearly illegal.¹³ It has been speculated that the General Staff of the German Army interpreted the Hague Convention as prohibiting anti-human, but not anti-animal biological warfare.

Development of biological weapons programmes leading up to and after World War II

10. A number of major states developed extensive biological weapons programmes in the years between the two world wars. Allied nations concentrated mainly on defensive programmes. Most offensive work focussed on anthrax, botulinum toxin and methods of preparation and delivery.¹⁴ The British produced five million cattle cakes laced with anthrax endospores that were to be dropped from planes over German farming land. Work also began on an apparatus that could produce clouds of bacteria to be inhaled by experimental animals, in order to determine the required doses. A bursting munition was tested against sheep on Gruinard Island off the coast of Scotland, using anthrax endospores as agent, which proved to be more powerful than any known chemical weapon.¹⁵ The Allies did not deploy these weapons in WWII, as they were meant to be used only in retaliation for an Axis attack with biological agents.

11. Germany decided not to use biological weapons in warfare, as their scientific experts did not think they were practical.¹⁶ In contrast, Japan pursued a huge offensive biological warfare programme, which ran from 1931 until 1945. At the infamous Ping Fan facility, located south of the city of Harbin, capabilities were developed for producing kilogram quantities of bacteria. Humans were used for experimentation, and Japan deployed biological agents in military field operations in China. This was the only documented use of biological weapons in WWII. Little work was done on viruses, rickettsiae or toxin agents.¹⁷

12. The US had an extensive biological weapons programme during and after World War II (see Box 3.2).

Box 3.2: US programme.

US Secretary of War Henry L. Stimson realised that “biological warfare is a dirty business”¹⁸ and wanted to legitimise the research by having civilians monitor it. A civilian advisory group was formed, and in mid-1942 it started handing out contracts that initiated secret work in 28 American universities. Work included exploring the

offensive potential of botulinum toxin and anthrax, which remained the bulk of the US bioweapons research effort during the war. In 1943, Fort Detrick, Maryland, called Camp Detrick at that time, became the site of these activities.¹⁹ The utility of biological agents was tested in closed chambers and in the open air.²⁰ The US programme did not, however, weaponise contagious agents.²¹ Towards the end of the war, the emphasis shifted from bacterial agents to defoliants, to be used against Japan's food crops.²²

Theodore Rosebury was a renowned microbiologist taking part. He had argued that “the likelihood that bacterial warfare will be used against us will surely be increased if the enemy suspects that we are unprepared to meet it and return blow for blow”.²³

²⁴ ²⁵

Rosebury actually believed that “the ethical concerns of the scientists in his laboratory governed the use of the weapons they were creating”²⁶. However, according to Bernstein, “history tells a different story” and “it seems clear that the key decisions were made in Washington, not in the laboratory”.²⁷

13. In light of the extensive development and production of biological warfare agents by several major states before and after World War II, combined with the realisation of the frightful potential of these weapons, the international community considered it imperative to negotiate a treaty that would regulate development and stockpiling of biological weapons, and thus be complementary to the Geneva Protocol²⁸, which prohibited use of these agents in warfare. These efforts resulted in the negotiation of the Biological and Toxin Weapons Convention (BTWC or BWC)²⁹, which was opened for signature on 10 April 1972; it entered into force in 1975. For examples of some agents of particular biological weapons relevance see Box 3.3.

Box 3.3: Some agents of particular biological weapons relevance.^a

<p>Bacteria (disease)</p> <p><u>Bacillus anthracis</u> (Anthrax)</p> <p><u>Yersinia pestis</u> (Plague)</p> <p><u>Francisella tularensis</u> (Tularemia)</p> <p><u>Vibrio cholerae</u> (Cholera)</p> <p><u>Burkholderia mallei</u> (Glanders)</p> <p><u>Burkholderia pseudomallei</u> (Meloidosis)</p>	<p>Viruses (disease)</p> <p>Ebola virus (Haemorrhagic fever)</p> <p>Crimean-Congo haemorrhagic fever virus</p> <p>Foot and Mouth disease virus</p> <p>Influenza-A viruses Subtype H5 or H7</p> <p>Lassa virus (Haemorrhagic fever)</p> <p>Marburg virus (Haemorrhagic fever)</p> <p>Tick-borne encephalitis virus</p> <p><u>Variola major</u> (Smallpox)</p> <p>Venezuelan equine encephalitis virus</p> <p>Yellow fever virus (Haemorrhagic fever)</p>
<p>Rickettsiae^b (disease)</p> <p><u>Coxiella burnetti</u> (Q fever)</p> <p><u>Rickettsiae prowazekii</u> (Typhus)</p>	<p>Toxins^c</p> <p>Botulinum neurotoxins</p> <p>Ricin</p> <p><u>Staphylococcus enterotoxin B</u></p> <p>Saxitoxin</p> <p>Several Mycotoxins</p>

^a Agents presented in the tables are some examples taken from: United Nations 2001³⁰; U.S. Department of Health and Human Services 2013.³¹

^b Rickettsiae are also bacteria, but are traditionally placed into a separate category because, unlike bacteria, most rickettsiae can only reproduce within animal cells (intracellularly).

^c Toxins are poisonous substances produced by living beings.

14. Human viruses were not discovered until the beginning of the 20th century, and little work was carried out on these agents in the run-up to World War II. This is reflected in a list of potential BW agents from 1940 to 1983, compiled by Erhard Geissler. According to this list, in 1940, of the agents known to be regarded by the military as potential biological weapons, only 4 were viruses. Viruses gained in

relevance as potential biological weapons over the years; by 1983, they had become the majority of recognised potential biological weapons agents.³²

15. Many more viruses were discovered in the 20th century. Beginning in the 1930s, rapid developments in technology generated studies on their description and physical properties. These technologies included methods for cultivation and purification of viruses as well as biochemical characterisation of these agents. Most significant, perhaps, was the development of the electron microscope, which enabled detailed descriptions of viral morphology.³³ Developments in biochemistry and molecular biology furthered the characterisation of viruses and other microorganisms as well. Viruses are more difficult to work with and cultivate than bacteria, so interest most likely grew as better methods for working with and cultivating them were developed, and some prophylactic vaccines and anti-viral treatments became available.

16. A similar case can be made for toxins. As they have many characteristics of toxic chemical agents, they are subject to control under both the Biological and Toxin Weapons Convention and the Chemical Weapons Convention. Chapter 8 discusses this in the context of the convergence of chemistry and biology. In 1940, only two toxins were considered as having the “highest liability for operational use”³⁴, whereas in 1983 the list of recognised potential toxin agents had increased to 19.³⁵ This increased interest in toxin agents over the years has been attributed primarily to the realisation of their increased toxicity compared to chemical weapons (see Table 3.1), progress made in aerosol dissemination of toxin agents, and the development of protective and prophylactic means.³⁶

Table 3.1: Comparison of potential toxin weapons (TW) and chemical weapons (CW).^a

Type	Substance	LD ₅₀ ^b in µg/70 kg	Heat Stability	Uptake over	
				Inhalation	Skin
TW	Botulinum	0.0021	±	++	–
	Ricin	1.40	–	++	–
	SEB ^c	91	±	++	–
	Mycotoxin T-2	35,000	+	++	+

	Myrotoxin B	560	+	++	+
	Saxitoxin	1,400	-	++	+
CW	Sarin	50,000	+	++	±
	VX	2,100	+	++	+

^a Values from Geissler 1986³⁷; Hacker and Heesemann 2000³⁸.

^b Doses lethal for 50% of those affected. Lethal doses for humans (at 70 kg body weight) approximated from values of toxin action on animals.

One microgramme (μ) = 10^{-6} gramme (g)

^c Staphylococcus enterotoxin B.

Development of second generation biological agents

17. A great deal of progress was made in the latter part of the 20th century in understanding the mechanisms of pathogenicity (the ability to cause disease or harm) and the interaction of microorganisms and toxins with the immune system. This knowledge was ushered in particularly by developments in genetics and molecular biology, which arose in the 1950s out of bacterial genetics, biochemistry and physiology. This in turn led to the development of genetic engineering in the early 1970s.³⁹ Immediately thereafter it was clear that the military had an interest in this new technique⁴⁰, which raised fears of military forces creating designer bioweapons that would be both novel and more efficient.⁴¹

Development of advanced (third generation) biological agents

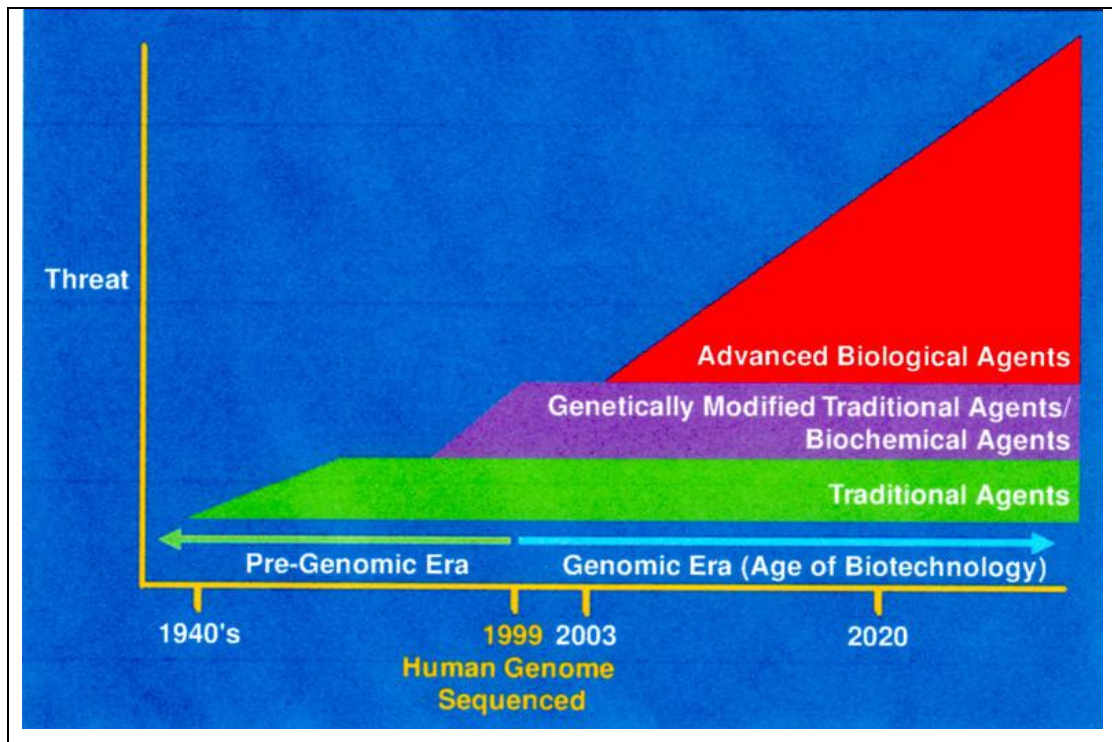
18. Following the advent of genetic engineering, the explosive growth in the areas of genomics, bioinformatics, synthetic biology, systems biology, nanotechnology and targeted delivery systems⁴² is, according to defence analysts, all contributing to a formidable increase in the bioweapons threat spectrum, i.e. the increase in numbers and kinds of biological agents (see Fig. 3.1).⁴³ In particular, synthetic biology and systems biology, which both rely on the enabling technologies of genomics and bioinformatics, have contributed considerably to the threat spectrum. Synthetic biology reaches beyond traditional recombinant DNA technology to the sophisticated

engineering of microorganisms to perform completely new tasks, by outfitting them with DNA-based biological circuits built from standardised biological parts. Sub-fields of synthetic biology are now reaching into the realm of creating artificial life from chemical components. Furthermore, the relatively new genome editing method using Clustered Regularly Interspaced Short Palindrome Repeats (CRISPR)/CRISPR-associated (Cas)9 endonuclease (CRISPR/Cas9) systems offers unprecedented potential for modifying genomes.⁴⁴

19. Systems biology tries to explain, with the aid of bioinformatics, how complex physiological systems interact with each other and function as a whole. In doing so, it discloses how bioregulators (biochemical molecules such as neuropeptides, neurotransmitters, hormones and cytokines) regulate the functions of physiological systems. This knowledge has in turn revealed the potential for manipulating vital functions such as respiration, cardiac activity, temperature, consciousness and immune defences in positive ways (towards better health), but also in negative ways detrimental to physiological function.⁴⁵ Bioregulators are regarded as potential agents in the context of both the BTWC and the Chemical Weapons Convention (CWC). See also Chapter 8 of this textbook for the relevance of these developments for the Chemical Weapons Convention.

Figure 3.1: The development of the biological agent threat spectrum over time.

(Source: Petro et al. 2003⁴⁶)



20. The development of the aerosol route for dissemination of biological agents did not really get underway until the first part of the 20th century. However, it was soon recognised that this was the most efficient way of disseminating biological warfare agents over large areas, and the aerosol route has over the years remained the preferred method of intended deployment.⁴⁷ In recent years, there have been substantial improvements in aerosol delivery of biological agents for therapeutic purposes, and nanotechnology in particular has played a central role in achieving this progress.⁴⁸

21. Advances in molecular biology, immunology and tumour genetics have led to the design of novel viral vectors for more directed delivery of therapeutic substances for vaccine development, cancer treatment, drug and immunotherapy purposes. In general, these viruses act as vehicles that carry and deliver foreign genes to the body. The foreign genes, which usually encode bioactive substances, have been incorporated into the viral genome by genetic engineering. Infection with the modified engineered virus leads to the expression of genes contained in the viral genome. This results in the synthesis of bioactive substance (the gene product) in the cells of the targeted tissues, so that this substance can then exert its effect. The dual-use implication here is that

these technologies could be used to arm viruses not only with bioactive therapeutics, but also with destructive or even deadly payloads, for example, a toxin or a particular bioregulator.

Use of advanced life sciences technologies in developing offensive biological weapons programmes

22. Several states that had the means used the new advances in life sciences technology for the development of offensive biological weapons programmes. Following the successful negotiation of the 1972 Biological Weapons Convention, all member states were required to destroy their stockpiles and stop all offensive biological weapons work. Many states continued with active programmes studying biological weapons, albeit for defensive purposes. Although there have been attempts to find criteria distinguishing between offensive and defensive biological weapons activities⁴⁹, it has proved very difficult in many cases.

23. As an example of the fine line between offensive and defensive activities, it was reported in 2001 that some secret activities of the US in the area of biological defence research could be taken as offensive biological weapons work.⁵⁰ One such activity involved the construction of a model of a small Soviet bomb filled with a biological agent (in this case a harmless simulant) with the aim of testing the dispersion properties of the agent contained in the bomb. It was argued that these tests were made in order to build a proper defence against such a weapon, but some observers argued that this work was in violation of Article I of the Convention, particularly the prohibition against the weaponisation of biological agents.⁵¹

24. Although the Soviet Union had signed and ratified the BTWC, it reportedly ran the largest offensive biological weapons programme of the twentieth century, which supposedly employed as many as forty to sixty thousand scientists, doctors, engineers and technicians in dozens of secret weapons facilities spread throughout the USSR.⁵² The Russian Government today and some former Soviet scientists claim that all the work performed in the former Soviet Union was for defensive purposes only.⁵³ This is of course in contrast to the reports of prominent defectors such as Ken Alibek (see

Box 3.4), Vladimir Pasechnik (a senior Soviet biologist who defected to the United Kingdom in 1989), as well as Igor Domaradskij (physician, administrator and bioweapons designer), who never defected but later revealed much about his work. Some of that work was indeed defensive, and in their detailed account of the Soviet biological weapons activities, Leitenberg and Zilinskas are careful to point out whether the work was offensive or defensive, and whether the scientists were successful or not in their attempts. Not all experiments were successful. Because so much has been revealed about the Soviet biological weapons programme, both the use of the most advanced methods in the life sciences to produce novel biological agents, as well as the weaponisation of these agents, can best be seen using this programme as an example. For another example of an offensive bioweapons programme see Chapter 16 of this book.

The special case of the former Union of Soviet Socialist Republics

25. Russia was hard hit by chemical weapons attacks in the WWI, suffering thousands of casualties. No doubt for this reason the Soviet Union wanted to be well prepared for possible future chemical and biological weapons threats. However, as a result of the purges during the 1930s and the rise of Lysenkoism in the 1940s, large numbers of biological specialists were arrested and some were charged with sabotage.⁵⁴ Trofim D. Lysenko (1898-1976) denied the existence of genes and advanced “pseudoscientific but politically attractive theories”⁵⁵ that gained the devotion of Stalin. As a result, the progress of Soviet biological sciences was impeded. The revitalisation of the Soviet Union’s programme began in the 1970s and ran at least until 1992, when President Yeltsin acknowledged its existence.⁵⁶ (See example 2 in Box 3.4 for an explanation for this revitalisation.)

26. During the period of revitalisation, the USSR Ministry of Defence established a new directorate (15th Directorate) which took over all issues related to biological weapons; it included a whole new network of facilities for biological weapons development and production, named Biopreparat.⁵⁷ Although supposedly a civilian enterprise, Biopreparat was actually directed by the military. The entire Soviet biological weapons programme received the codename “Problem Ferment”.⁵⁸

27. To give an idea of the capability of the system, a major Biopreparat facility was said to be able to produce two hundred kilograms of weaponised, contagious plague agent (*Yersinia pestis*) each week. In addition to the well-known biological weapons agents such as those causing anthrax, tularemia and glanders, work was done on highly lethal viruses including Ebola virus, Marburg virus and the smallpox virus, with the goal of their weaponisation. Also, as a result of the modernisation of Soviet science, methods employing the newest developments in the fields of genomics, neurobiology, immunology and systems biology were applied in the most sophisticated research and development experiments, ranging from attempts to render highly pathogenic bacteria resistant to multiple antibiotics, on through to the creation of bacteria-virus and virus-virus chimeras, as well as the development of bioregulators as weapons to disrupt physiological functions. A few examples of these experiments with their goals are outlined in Table 3.2.⁵⁹ The Soviet Union also carried out extensive testing of the weapons, particularly at the major test site on Vozrozhdeniye Island in the Aral Sea. There are still questions about the status of the programme today, because no official account of any credibility has been produced and some military facilities have remained closed to outsiders.⁶⁰ Reasons for the participation of Soviet scientists in the offensive biological weapons programme are offered in Box 3.4.

Table 3.2: Examples of the application of modern biotechnologies to the creation of novel biological agents carried out in the Soviet Union at two major Biopreparat institutes, Obolensk and Vector.^a

Experiment	Goal
<i>Y. pestis</i> + diphtheria toxin gene	Increased virulence of <i>Y. pestis</i>
Vaccinia virus ^b + Ebola virus gene	Effect haemorrhage
<i>B. anthracis</i> + <i>B. cereus</i> hemolysin	Modulation of immunity to <i>B. anthracis</i> vaccines
<i>Y. pestis</i> + VEE virus cDNA with Te promoter	When infected persons are given antibiotics, <i>Y. pestis</i> is destroyed but this would activate the production of VEE virus
Vaccinia virus ^b + genes for beta-	Affect analgesic function

endorphin	
Vaccinia virus ^b + VEE virus structural gene	Increased virulence
Vaccinia virus ^b + Ebola virus structural gene	Increased virulence

^a Source: Leitenberg and Zilinskas⁶¹, especially chapters 7, 8 and 9; Gilsdorf and Zilinskas 2005⁶²; Domaradskij and Orent 2003⁶³.

^b Vaccinia virus (used as a vaccine) was used for these experiments as a surrogate for variola virus (causative agent of smallpox), but presumably the same manipulations could be done with variola virus; indeed, this work was apparently planned after getting the manipulation to work using the safer vaccinia virus; this was, however, never carried out with variola virus.⁶⁴

Box 3.4: Motivation of scientists working in the former Soviet Union on biological weapons for offensive purposes.

Why did the Soviet Union pursue such a course, particularly after signing and ratifying the 1972 Biological and Toxin Weapons Convention as a depository?

1. Having the ability to retaliate in reply to a perceived enemy biological weapons threat and attempting to balance out the supposed superiority of the other side:

Example: Kanatjan Alibekov (Ken Alibek) is a physician who worked as chief scientist for Biopreparat from 1975-1992 and became its Deputy Director in 1988. He defected to the US in 1992. When asked in an interview conducted by Jonathan Tucker why young medical scientists like himself worked on biological weapons, he replied: “At first I had a lot of doubts because I had given my oath as a physician not to cause harm. But you need to imagine the internal political situation in the Soviet Union. For many years we were told that we needed to protect our country from a very strong enemy, armed with sophisticated weapons, that wanted to destroy us - the United States and its NATO allies. We were also told that there was reliable intelligence that the United States was continuing to develop biological weapons, and that our program was a response to the US program.”⁶⁵ He said that when you are told that day after day, “this propaganda unfortunately works perfectly”.

2. The quest of scientists for support of biotechnological research by the government:

Example: Yury A. Ovchinnikov

The theories of Lysenko during the Stalin era had severely retarded Soviet scientific progress, above all in the fields of molecular biology and genetics⁶⁶. Indeed, Soviet scientists were very much concerned about the growing backwardness of their science, so “in order to give biology sufficient political support to overcome these problems, some academicians and Soviet officials argued for increasing support for the biological sciences in terms of their military significance”.⁶⁷ Ovchinnikov, who was a biochemist, became director of the M.M. Shemyakin Institute of Bioorganic Chemistry in 1970. Because of his application of modern biotechnology techniques to biological weapons development, he was very influential in establishing the renewed, massive biological weapons programme.⁶⁸ Although several sources have stated that Ovchinnikov was not personally interested in biological weapons development, he was, “in a favorable position to explain the importance of modern biotechnology for military...applications”⁶⁹. He was said to have “stressed the need to solve scientific problems related to BW using new biotechnology techniques and that doing so was vital to national defense”.⁷⁰ Apparently, this line of arguing for increasing scientific support in terms of military significance was effective.⁷¹

Conclusions

28. It can clearly be seen that advances in the modern life sciences technology throughout the years have always attracted the immediate attention of the military, including use as in World War I and World War II, and thereafter to create novel biological agents and weapons for offensive purposes. The fact that such novel agents were never put to use in warfare is significant, but secondary to the intent behind their development.

29. This chapter describes state-supported biological weapons programmes. As a general rule, and as history tells us (see Chapter 4 of this book), we can assume that the more complicated the technology required, the less likely that it currently presents a terrorism risk. As described in Chapter 4, specialist and tacit knowledge, and also the current state of the “de-skilling process”, all play important roles, which means that the terrorism risk is particularly difficult to assess.

30. In practice, it is not easy to successfully implement complex biotechnological methods. This requires expertise acquired over many years, specially equipped laboratories and production facilities, as well as considerable funding. Therefore, technically elaborate processes are more likely to be implemented by researchers or other persons who enjoy the support of large institutions and can look back on many years of practical experience. The present opinion of experts, backed up by the few well documented terrorist attacks involving biological weapons that have occurred so far (see Chapter 4), is that terrorists who are not themselves conducting corresponding high-tech research will tend to fall back on naturally occurring agents and traditional biological weapons.

31. Despite suspicions, the biological weapons development programme of the former Soviet Union was successfully concealed, both within the Soviet Union and abroad. Similarly, speculation about the offensive biological weapons activities of certain “rogue” states remains only suspicion. This leads us directly to the lack of an effective means within the Biological and Toxin Weapons Convention for monitoring and determining compliance (see Chapter 6 in this Guide). We have to ask the question as to whether the warnings of Matthew Meselson have never really been taken seriously enough for the international community to deal properly with the risk of misuse of the advances in the life sciences? Several chapters in this book, in particular Chapters 2, 6, 7, 8 and 18, address this question of lack of effective measures governing dual-use work in the life sciences and related fields, and suggest ways of dealing with the problem.

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Chapter 4: Biological weapons as weapons of terror: perspectives on the threat

Catherine Jefferson

Key learning objectives

- i. Understand the concept of bioterrorism and the reasons why biological weapons may be attractive to terrorists;
- ii. Identify and analyse three confirmed attempts to use biological weapons against humans for terrorist purposes;
- iii. Develop an appreciation of the need for more nuanced assessments of the threat of high-tech, high-impact bioterrorism, which takes into account the role of tacit knowledge and the challenges of effective weaponisation.

Introduction

1. The threat of bioterrorism has become increasingly salient in contemporary security policy, yet actual incidents of bioterrorism have remained rare, low casualty events. This chapter provides historical perspectives on the bioterrorism threat and examines the practical barriers that limit what such malevolence could realistically achieve. It begins by exploring the reasons why biological weapons may be attractive to terrorists, and goes on to describe three confirmed attempts to use biological weapons against humans for terrorist purposes: the 1984 use of Salmonella by the Rajneesh cult in Oregon, the United States of America; the 1990-1995 attempted use of botulinum toxin and the causative agent of anthrax by the Aum Shinrikyo cult in Tokyo; and the 2001 anthrax letters attacks in the United States of America attributed to the biodefence scientist Bruce Ivins. The chapter draws on these case studies and introduces social science literature on tacit knowledge to examine the barriers to weaponisation faced by would-be bioterrorists seeking to cause high casualty, high impact events. The chapter goes on to describe current concerns that developments in

science and technology are eroding these barriers, focusing specifically on developments in synthetic biology and the emergence of a do-it-yourself community, and concludes by exploring recent scholarship that calls for more nuanced assessments of the bioterrorism threat.

Biological weapons as weapons of terror

2. A biological weapon (or bioweapon) is a weapon intended to cause harm through the infectivity of disease-causing organisms (such as bacteria, viruses, rickettsiae or fungi) or through the effects of toxins produced by living organisms or synthesised in a laboratory. Biological weapons can take many forms and can vary significantly depending on the intended effect, be it to attack (humans, other animals, or plants), incapacitate, contaminate terrain for long periods, or trigger a major epidemic.

3. Agents selected for development in past military programmes have included bacterial agents that cause anthrax, brucellosis, glanders, tularaemia and plague; viral agents that cause Venezuelan equine encephalitis, Marburg haemorrhagic fever, Ebola and smallpox; rickettsiae such as Coxiella burnetii, which causes Q fever; fungi such as Pyricularia oryzae, which causes rice blast and is a destructive plant pest; and toxins such as botulinum toxin, ricin and saxitoxin. In order to be effective as weapons of warfare, biological agents must be capable of being produced in large quantities, they must be stable enough to maintain viability during production, storage and transportation, and they must be combined with an appropriate delivery system to ensure efficacy when disseminated.

4. Bioterrorism is the use of biological weapons to cause death, fear, economic disruption and/or political upheaval in order to achieve political, ideological, social and/or religious goals.¹ The term bioterrorism is complicated by the potential for terrorism to be State-sponsored, as well as the potential for certain acts to be perpetrated by individuals not motivated by political goals, but rather for the purposes of extortion or revenge (sometimes called “biocrimes”). Broadly, the use of biological agents by individuals or groups not otherwise recognised as an extension of the government of a State constitutes bioterrorism.

5. Depending on the objectives of a terrorist group, reaching high levels of sophistication in terms of the development and weaponisation of biological agents may not be necessary. Indeed, one reason why biological weapons could be attractive to terrorists is because of their psychological impact. These characteristics of biological weapons can make the threat of bioterrorism elicit exceptionally high levels of dread² and, if a bioterrorism attack was to take place, its characteristics could generate a level of societal disruption vastly disproportionate to the burden it poses in terms of illness and death. From this perspective, the development of a sophisticated bioweapon would not be necessary if the goal is simply to create panic and fear. Moreover, while some terrorists, particularly religiously motivated groups, could be attracted to biological weapons because of their potential to fulfil apocalyptic visions of mass murder, others groups could be attracted to biological weapons as a means to incapacitate large numbers of people without necessarily killing anyone.

Historical cases of bioterrorism

6. There have been three confirmed attempts to use biological weapons against humans for terrorist purposes: the 1984 use of Salmonella by the Rajneesh cult in Oregon, the 1990-1995 attempted use of botulinum toxin and anthrax by the Aum Shinrikyo cult in Tokyo, and the 2001 ‘Amerithrax’ distribution of a high-quality dry-powder preparation of anthrax spores attributed to the biological weapons scientist Bruce Ivins. In addition to these incidents, there have been other attempts to develop biological agents, as well as thousands of hoaxes, or false claims, that a biological attack has been perpetrated.³

The 1984 use of Salmonella by the Rajneesh cult

7. In August and September 1984, a religious cult known as the Rajneeshees employed Salmonella to deliberately contaminate salad bars and other public places in The Dalles, a small town in Oregon, the United States of America, resulting in 751 reported victims of food poisoning. This event is one of the most significant incidents

of bioterrorism, as it was the first successful and single largest such attack in the history of the United States of America.

8. The Rajneeshee cult was founded in India in the 1960s by the Bhagwan Shree Rajneesh, known to his followers as an 'Enlightened Master'. The cult attracted considerable following in Europe and the United States of America in the 1970s and included wealthy members, lawyers, and lab technicians. The cult generated controversy due to its rejection of traditional values and, by 1980, the Rajneeshees were facing increasing hostility from the Indian government. Under the advice of one of his followers, Ma Anand Sheela, the Bhagwan emigrated and relocated the group to the United States of America. The Rajneeshees established a commune on a large ranch located in Wasco County, Oregon.

9. Due to the cult's controversial beliefs, the Rajneeshees' relationship with the local inhabitants was strained, and this intensified over conflicts relating to land-use and the commune's expansion, particularly when the cult took political control of Antelope, a small town nearby.⁴ The Rajneeshees also violated Oregon state laws on land use, which limit building on undeveloped land. To evade zoning restrictions, the Rajneeshees incorporated a town on the ranch, named Rajneeshpuram. By early 1984, with hostility continuing, Oregon's Attorney General conducted an investigation into the legal status of Rajneeshpuram and stated that the municipality was unconstitutional because there was no separation between church and state.

10. In order to outmanoeuvre the Attorney General, high-ranking members of the cult planned to make Wasco county residents too sick to vote in the November elections for County Commissioner, enabling the Rajneeshees to control the vote and seat a candidate who would be favourable towards the Rajneeshees. Fewer than a dozen people, all senior members of the Rajneeshee cult, participated in planning the biological attack. Sheela, who had nominally become the Bhagwan's personal secretary, worked closely with Ma Anand Puja, a registered nurse who headed the commune's health centre and was also part of the "inner circle" of the cult.⁵ Puja obtained samples of Salmonella typhimurium by using the credentials of the medical facilities in Rajneeshpuram. A secret laboratory was established in a remote part of the commune where production of Salmonella typhimurium took place.

11. The Rajneeshees' first recorded use of biological agents took place on 29 August 1984, when water laced with Salmonella typhimurium was given to two Wasco County Commissioners, known to be hostile to the cult, during their visit to Rajneeshpuram. Both became sick and one required hospitalisation.⁶ The cult also used Salmonella cultures on several other occasions – dumping them into one of the local water systems, spreading them on produce in a supermarket and on doorknobs and urinal handles in the county courthouse – but all without apparent effect.

12. The most significant use of biological agents occurred in September 1984, when the Rajneeshees targeted restaurants in the town of The Dalles, the county seat. As a test run for the November election, members of the cult contaminated salad bars in several restaurants with Salmonella typhimurium, resulting in 751 people becoming ill. The local health officials identified Salmonella as the cause within just a few days of the outbreak, but the Rajneeshee cult's responsibility was not established until a year later. The outbreak occurred in two waves, appearing to be the result of at least two incidents of deliberate contamination – the first at two restaurants around 8 September, the second at ten or more restaurants around 21 September.⁷

13. No further attacks were made and the Rajneeshees abandoned their attempts to manipulate the election by early October, when it became clear that their plot would fail. A few months after the November election, the commune fell apart due to internal conflict and a large number of lawsuits going against them. Teams of state and federal agents investigated the commune, during which Salmonella cultures were found that were matched to the outbreak. Sheela and Puja, as well as several other senior members of the Rajneeshee cult, fled to Europe in September 1985. However, Sheela and Puja later returned to the United States of America and agreed to a plea bargain. Among other sentences, they were charged with product tampering for the Salmonella poisonings in The Dalles.⁸

The 1990-1995 attempted use of botulinum toxin and anthrax by the Aum Shinrikyo cult

14. The Aum Shinrikyo (“Supreme Truth of Aum”), a Japanese religious cult founded by Shoko Asahara, attempted several acts of bioterrorism. Unlike the Rajneeshees, the goal of the Aum was to create massive and widespread fatalities. Better known for its successful sarin attacks on the Tokyo subway in 1995, which resulted in twelve fatalities and over a thousand casualties, the Aum Shinrikyo believed that too many people were accumulating bad karma and believed that the corrupted world needed to be destroyed in order to create a new, pure society.

15. In 1984, Asahara established a small yoga school called Aum No Kai (‘Circle of Aum’), which in 1987 was transformed into Aum Shinrikyo and given official religious status by the Tokyo metropolitan government in 1989. Estimates of the Aum membership vary, but one suggestion is that by 1995 the cult had around 40,000 members worldwide, including 10,000 in Japan, around 30,000 in Russia, and several scattered in the United States of America, Germany and elsewhere.⁹

16. The Aum Shinrikyo’s doctrine emphasised salvation and conceived of two strategies for its facilitation. As Wheelis and Sugishima note, “One was to form a majority in the Diet (parliament) and take control of the Japanese political system. The Aum’s practices could then be implemented nationally. The second strategy was to destroy Japan by forceful means for the purpose of purification”.¹⁰ Asahara attempted the legitimate route first when, in 1990, several Aum candidates, including Asahara, ran for the Japanese parliament. However, all of these candidates were largely ignored by Japanese voters. This appears to have been a turning point for Asahara, who believed that salvation would now have to be achieved through force. It appears that at this point the cult launched its weapons programme, aided considerably by the number of young scientists and technicians who had joined the cult, including those with backgrounds in physics, chemistry and biology.

17. The Aum Shinrikyo allegedly had interest in developing several biological agents, including botulinum toxin and the causative agents of anthrax, Q fever and Ebola.¹¹ In the early 1990s, the Aum Shinrikyo made efforts to develop and disseminate two

agents – botulinum toxin and anthrax bacteria. Aum scientists tried to isolate Clostridium botulinum from soil samples, although there is no evidence that they were successful. Where the strain that was ultimately used came from is unknown. In addition to the problems of isolating botulinum toxin, culturing the bacterium, producing it and developing the product into a feasible weapon also presented considerable challenges. A crude extract of the toxin from the cultured agent was dried and powdered, and several dissemination methods were attempted.¹² One attempt involved the dissemination of botulinum toxin from vehicles equipped with a spray device. The United States of America naval base at Yokosuka, the Imperial Palace and government buildings were targeted. Another attempt involved the dissemination of botulinum toxin from briefcases designed to release the toxin. Despite these and other attempts, no casualties were reported.

18. The Aum's attempts to weaponise anthrax bacteria were equally unsuccessful and it appears that an avirulent strain of the agent (possibly a stolen vaccine strain) was obtained.¹³ In one dissemination attempt, the Aum sprayed the agent (most likely crude culture, unprocessed in any way) from the roof of their headquarters building in Tokyo. For the dissemination, the Aum set up two sprayers on the roof of the eight-story building, each within a large round cooling tower. Pipes were extended from the cooling towers to tanks below, which were filled with a liquid suspension of anthrax bacteria.¹⁴ The device worked poorly, producing large droplets rather than the very fine aerosol needed for effective transmission of anthrax. Several complaints from local residents about foul odours emanating from the building led to increased police attention and, ultimately, the Aum ceased the spraying operation and vacated the site. In another dissemination attempt, targeting the area around the Kanagawa prefectural office and the Imperial Palace, the Aum equipped vehicles with spraying devices, but according to prosecutors' statements, the nozzle of the sprayer clogged and the operation failed.¹⁵

19. Despite having considerable resources and expertise at its disposal, the Aum was unsuccessful in causing any casualties through the use of biological agents. As Leitenberg notes, "The group reportedly has available to it extraordinary financial resources, in the tens and hundreds of millions of dollars, some of which it converted into the procurement of equipment and facilities for work on these agents [Botulinum

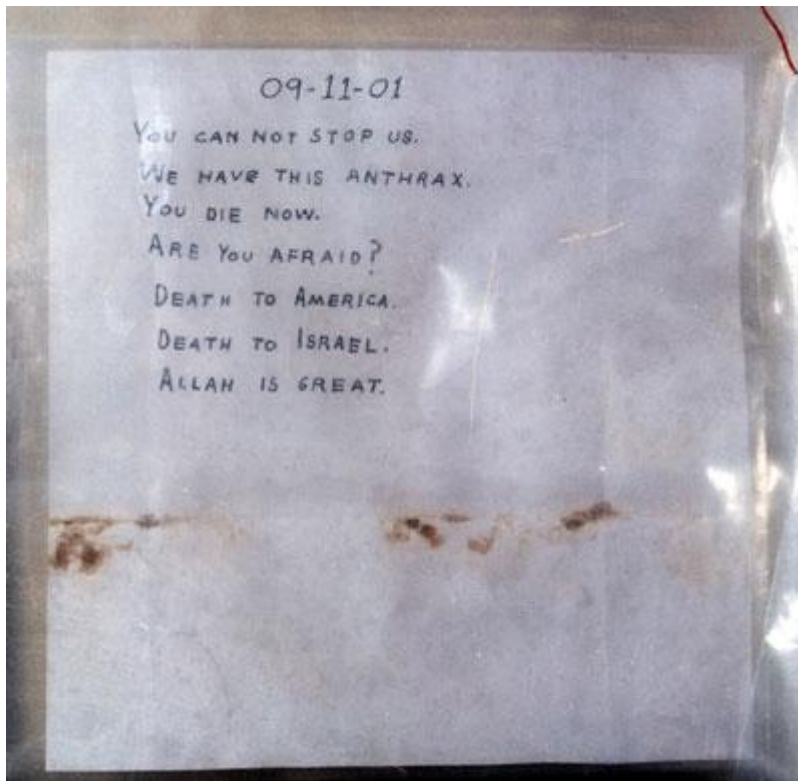
toxin and anthrax bacteria]. Their efforts in the biological weapons area took several directions, but despite semi-professional capabilities, substantial time and effort, all of these efforts failed.”¹⁶

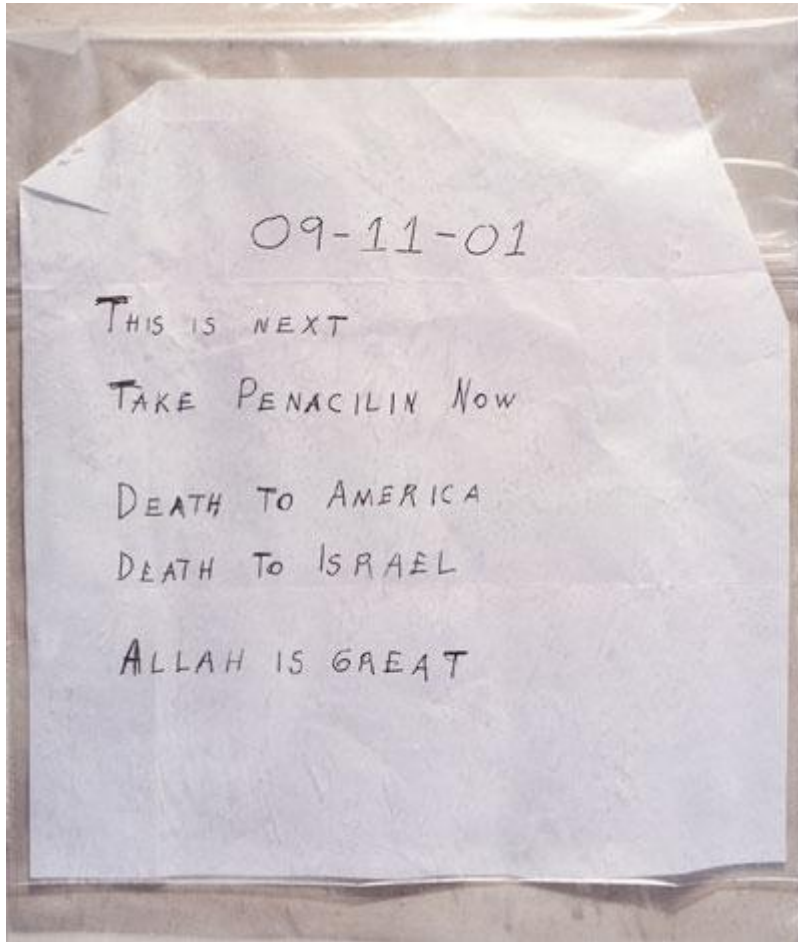
The 2001 anthrax attacks

20. The 2001 anthrax letters attacks in the United States of America, also known as ‘Amerithrax’ after its Federal Bureau of Investigation case name (see Chapter 12), occurred over the course of several weeks, beginning 18 September, just one week after the 9/11 terrorist attacks. 9/11 saw the destruction of the World Trade Center in New York City, damage to The Pentagon in Arlington, Virginia, and the crash of an airliner in Shanksville, Pennsylvania. These attacks killed over 3,000 people and caused billions of dollars of damage to property and infrastructure. Although the events of 9/11 were not in any way related to biological weapons, the conjunction of the high impact, coordinated attacks of 9/11 with the anthrax letters attacks that soon after followed, served to significantly heighten concerns about the threat of bioterrorism.

21. The anthrax letters attacks came in two waves.¹⁷ The first set of anthrax letters had a Trenton, New Jersey postmark dated 18 September 2001 (Figure 4.1). Five letters containing anthrax spores were mailed to ABC News, CBS News, NBC News and the New York Post, all located in New York City, and to the National Enquirer at the American Media, Inc. in Boca Raton, Florida. All of these letters were initially dismissed as routine hate mail. However, on 3 October, the first victim was diagnosed in a Florida hospital and teams from the Centers for Disease Control were dispatched to investigate the source of infection. When the Centers for Disease Control discovered anthrax endospores in the victim’s workplace, the Federal Bureau of Investigation assumed control of the investigation. It was not until 12 October, a week after the first victim died, that it became clear that the letters were the source of multiple anthrax infections.

Figure 4.1: The Anthrax Letters. (Source: The Federal Bureau of Investigation, Famous Cases & Criminals, Amerithrax Case, <http://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax/the-envelopes>)





22. Two more anthrax letters were sent three weeks after the initial attack, dated 9 October, and addressed to two Democratic Senators in Washington DC, Tom Daschle of South Dakota and Patrick Leahy of Vermont. The Daschle letter was opened by an aide on 15 October and the powder was quickly identified by Capitol Hill police as anthrax endospores. This resulted in the shutdown of the government mail service and the massive distribution of antibiotics to employees at the building. The unopened Leahy letter had been misdirected and was later discovered in an impounded mailbag.

23. In total, the anthrax letters attacks resulted in at least 22 cases of anthrax, five of which were fatal. Many of the victims were postal workers exposed to anthrax endospores through leakage from the letters. Throughout the crisis, the Centers for Disease Control and local health officials provided some 33,000 people with post exposure drugs (usually Ciprofloxacin). At least 17 buildings were confirmed to have been contaminated with anthrax endospores and decontamination efforts are estimated to have totalled around \$320 million.¹⁸

24. Given the content of the letters and the proximity to the 9/11 attacks, initial threat assessments – and blame – pointed to Al Qaeda. Indeed, following the attacks, several newspaper reports suggested the anthrax agent came from Iraq and speculated about the possibility of a link between the anthrax attacks and Al Qaeda.¹⁹ However, it soon became apparent that the source of the attacks could be a United States of America Government connected scientist. While the letters sent to the media contained a coarse brown material, the anthrax endospore preparations found in the letters sent to the Senators were of extraordinary high quality and pointed to a skilled scientist and a state-sponsored program.

25. All of the material found in the anthrax letters was derived from the same bacterial strain – the Ames strain, one of eighty-nine known strains of the anthrax bacterium. This strain was initially isolated from a dead cow in Texas in 1981 and shipped to the United States Army Medical Research Institute of Infectious Disease in Fort Detrick, Maryland. However, this strain had been subsequently shared with research laboratories around the world, making the source of the strain difficult to pinpoint, although it did narrow the range of possibilities. The Federal Bureau of Investigation subpoenaed samples from laboratories known to possess the Ames strain of anthrax bacteria and collected them in a repository. The material derived from the anthrax letters was examined for additional unique features that could then be compared to samples obtained from laboratories holding the Ames strain. Based on the testing, the Federal Bureau of Investigation determined that the material was directly related to a single Ames strain identified as RMR-1029.²⁰ Dr. Bruce Ivins, a biodefence scientist at Detrick (Box 4.1), was the sole custodian of RMR-1029.

Box 4.1: Bruce Ivins and the Insider Threat.

Bruce Ivins was a trained microbiologist who worked as a senior biodefence researcher at Detrick for 18 years and was the co-inventor of two United States patents for anthrax vaccine technology. Ivins committed suicide on 27 July 2008 after investigators informed him of his impending prosecution for the anthrax letters attacks. Following this, allegations arose about Ivins' mental health, with claims that he suffered from episodes of paranoia and depression.²¹ Concern over this potential

insider threat from laboratory workers has led to an increased focus on personnel reliability programmes to vet people permitted to access high-containment laboratories and select agents.²² However, the value of such programmes has been called into question, particularly given that Ivins would have already been subject to personnel evaluation to work at Detrick.²³

26. In August 2008 the Federal Bureau of Investigation named Ivins as the ‘Amerithrax’ perpetrator, claiming he wanted to bolster support for a vaccine he had helped create. Ivins committed suicide a few days before the announcement, having been told the Federal Bureau of Investigation was about to press charges against him. With his death the Federal Bureau of Investigation evidence will not be tested in court, but some experts have questioned whether a definitive conclusion could be reached on the basis of the available scientific evidence alone.²⁴ Despite this uncertainty it seems clear that very few people in the world have the sort of training required to make anthrax endospore preparations of the quality seen in the anthrax letters.

Assessing the threat: the barriers to bioterrorism

27. Following 9/11 and the anthrax letters attacks, concerns about the catastrophic potential of bioterrorism increased dramatically.²⁵ For example, shortly after the attacks, President George W. Bush asserted that, “This threat [of bioterrorism] is real and extremely dangerous. Rogue states and terrorists possess these weapons and are willing to use them.”²⁶

28. Despite the fact that few incidents of bioterrorism have been recorded and, even in those cases where a viable biological agent has been deployed there have been relatively few deaths, the threat of bioterrorism is frequently portrayed in terms of its massive destructive potential. However, this framing of the bioterrorism threat fails to take into account the challenges involved in successfully acquiring and weaponising a biological agent. Indeed, interested groups would require access to significant financial resources, expertise and high-technology facilities in order to create a

sophisticated biological weapon capable of causing massive destruction, and they would be faced with challenges at every stage of the process.

29. First, acquiring or producing a suitable biological agent is problematic for a number of reasons. For example, attempts to acquire a viable biological agent could make a group more vulnerable to detection by authorities, and handling pathogenic organisms presents dangers to the individuals involved, particularly if they lack adequate biosafety training and infrastructure. More fundamentally, producing and culturing a biological agent requires considerable knowledge and expertise. For example, Aum scientists failed to produce virulent strains of the causative agents of both botulinum toxin and anthrax, and very few people in the world have the sort of training required to make anthrax endospore preparations of the quality used in the anthrax letters attacks. Moreover, this type of expertise often requires tacit knowledge. Broadly, tacit knowledge refers to skills and techniques that cannot be readily codified but, rather, are acquired through a process of ‘learning by doing’ or ‘learning by example’, and often take considerable time and effort to gain.²⁷ This suggests that a significant level of skill and know-how is required to develop and handle biological agents.

30. Next, in addition to the difficulties of acquiring a suitable biological agent, large-scale production of the biological agent poses further challenges. Drawing on the difficulties faced by the Iraqi, Soviet, and the United States of America biological weapons programmes, Sonia Ben Ouagrham-Gormley explains: “Scaling up fragile microorganisms that are sensitive to environmental conditions and susceptible to change — and viruses are more sensitive than bacteria — has been one of the stiffest challenges for past biological weapons programs to overcome, even with appropriate expertise at hand. Scaling-up requires a gradual approach, moving from laboratory sample, to a larger laboratory quantity, to pilot-scale production, and then to even larger-scale production. During each stage, the production parameters need to be tested and often modified to maintain the lethal qualities of the agent; the entire scaling-up process can take several years.”²⁸

31. Finally, even if these barriers could be overcome, the biological agent would still require some means of dissemination to be an effective weapon. Aerosolisation would

be the most effective means of weaponising a biological agent to create mass casualties, but, as the failures experienced by the Aum Shinrikyo attest, this involves major technical hurdles. As Jefferson, Lentzos and Marris explain, “To infect through the lungs, infectious particles must be microscopic in size – between 1 and 5 μm in diameter. Terrorists would therefore have to develop or acquire a sophisticated delivery system capable of generating an aerosol cloud with the necessary particle size range and a high enough agent concentration to cover a broad area. Overall, an important trade-off exists between ease of production and effectiveness of dissemination.”²⁹ The successful delivery of an aerosolised biological agent would also depend on other contingencies, such as prevailing atmospheric conditions and the public health response of the targeted region, which creates further uncertainties.

32. Concerns have been expressed that developments in science and technology could lower the barriers to the development of biological weapons, therefore making them more accessible to terrorists. For example, addressing delegates at the five-yearly meeting of the Biological and Toxin Weapons Convention in 2011, the United States of America Secretary of State Hillary Clinton asserted, “The advances in science and technology make it... easier for states and non-state actors to develop biological weapons. A crude, but effective, terrorist weapon can be made by using a small sample of any number of widely available pathogens, inexpensive equipment, and college-level chemistry and biology.”³⁰

33. The field of synthetic biology (see Chapter 3) has elicited particular concerns in this regard.³¹ One of the key founding principles of synthetic biology has been a commitment to making biology “easier to engineer”. The underlying vision is that synthetic biology will produce well-characterised biological parts that can be easily obtained from open source online registries and then assembled into genetic circuits, devices and systems that will reliably perform desired functions in live organisms.

34. This vision has raised concerns that synthetic biology could make it easier for terrorists to exploit biology for hostile purposes. Fears have been expressed that synthetic biology will lead to “de-skilling” and that, combined with open online access to the genomic DNA sequences of pathogenic organisms and the reduction in price for DNA synthesis, this will make biology increasingly accessible to people

operating outside well-equipped professional research laboratories - including people with malevolent intentions. The emergence of the student international Genetically Engineered Machine (Figure 4.2) competition has come to epitomise this supposed trend towards greater ease of access and the associated potential threat from rogue actors.

35. However, recent social science scholarship suggests that these concerns tend to exaggerate the risk of misuse, and underestimate the continued importance of factors such as tacit knowledge.³² Indeed, the experiences of student teams tend to demonstrate the challenges of successfully performing synthetic biology experiments, and highlight the ongoing need for guided instruction and the specialist skills acquired through trial and error. The same can be said of the do-it-yourself biology community, whose appearance has raised fears among some observers that unregulated amateur tinkering with advanced technologies might produce dangerous biological agents that can be used for hostile purposes. However, other observers maintain that the current capabilities of do-it-yourself biologists are overrated.³³ Moreover, even if advances in some areas of the life sciences and related fields do erode the need for certain elements of tacit knowledge by de-skilling aspects of life science experimentation, weaponisation for mass casualty impact would still remain extremely challenging. This suggests the need for more nuanced assessments of the threat of high-tech, high-impact bioterrorism posed by developments in science and technology, which takes into account these challenges.

Figure 4.2: The international Genetically Engineered Machine competition has come to epitomise the supposed trend towards de-skilling. (Source: http://www.igem.org/Main_Page)



Conclusion

36. There have been few historical attempts to use biological weapons as weapons of terror, and where biological weapons have been used, they have been relatively crude, low casualty events. Following 9/11 and the anthrax letters attacks, the perception of the catastrophic potential of bioterrorism increased dramatically. Despite these concerns, there are practical and technical barriers at all stages of the weaponisation process that limit what malevolent actors could realistically achieve. Current concerns about the threat of bioterrorism tend to focus on developments in science and technology and the emergence of a do-it-yourself community, and the greater ease of access these technologies could offer. Some social science scholars argue that more nuanced assessments of the bioterrorism threat posed by advances in science and technology are needed, that take into account the role of tacit knowledge and the challenges of weaponisation.

37. However, although it is currently unlikely that terrorists would be able to apply the advances in the life sciences and related fields to produce an effective, novel biological weapon, this is not to suggest that there is no threat.³⁴ It remains important to take measures to prepare against the possibility of a biological weapons attack, and policy action is necessary at all levels, from prevention through preparedness to consequence management. Moreover, the increasing proliferation of life science capabilities and access to materials could increase the threat of smaller scale incidents of bioterrorism, and scientists have an important role to play in taking responsibility for the protection of their research from any possible misuse.

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Chapter 5: Natural outbreaks and biosecurity: The 2014 Ebola outbreak

Maureen Ellis

Key learning objectives

- i. Understand the threats from individuals with malicious intent exploiting natural disease outbreaks for harmful purposes;
- ii. Understand the biosecurity threats from the 2014/2015 outbreak of Ebola in West Africa as a recent example;
- iii. Understand that effective biosecurity measures should be locally-relevant, practical, and should build upon complementary biosafety and outbreak control activities;
- iv. Understand the importance of competent biosecurity professionals from multiple sectors, including academia and students, working together to reduce biosecurity risks in disease outbreak settings.

The biosecurity threat from infectious disease outbreaks

1. The World Health Organization defines a disease outbreak as the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season. An outbreak may last for a few days, weeks or months, and may occur in a restricted geographical area, or may extend over several countries. A single case of an infectious disease long absent from a population (e.g. smallpox), or one that is caused by a biological agent not previously known, could also constitute an outbreak. While a disease outbreak may be either a naturally-occurring disease outbreak or a deliberately-caused disease outbreak involving the intentional release of disease agents to cause harm, most outbreaks are naturally

occurring. Some outbreaks have had global reach by exploiting our interconnectedness through air travel and trade (e.g. Swine Flu, Avian Flu and Severe Acquired Respiratory Syndrome (SARS)), but far more often countries and regions experience localised outbreaks such as Ebola Virus Disease and Middle East Respiratory Syndrome (MERS), which can devastate communities with illness, loss of life and shattered livelihoods. Severe Acute Respiratory Syndrome (SARS), which claimed nearly 800 lives, resulted in an estimated \$50 billion in global losses. The economic impact of a deliberate release could reach an estimated \$26 billion per 100,000 persons exposed.¹ Responding to future large-scale and sustained outbreaks requires an effective response capacity from the international community, including the mobilisation of a diversity of human resources to strengthen national response measures. In addition to healthcare professionals, academic students at the undergraduate and graduate level, and volunteers, can play a vital role in the multisectoral response to disease outbreaks (Box 5.1).

Box 5.1: Local university students become active in the Ebola outbreak response²

Ever since the closure of the university due to the Ebola outbreak, Tony Harrison, sociology student at the University of Liberia, has been trying to help stop the spread of the Ebola virus in his country. He joined the team of active case finders to go from house to house to find out if sick people are being treated. “What makes this activity important is that it will help us to quickly get rid of Ebola out of the country. It will help to save lives in my community and maybe in my own family. I really would like to return to my normal life and go back to school.”



WHO/P. Desloovere

Tony Harrison (pictured on the left), student, University of Liberia

2. By constructing a database of emerging infectious disease events between 1940 and 2004, Daszak concludes that, decade by decade, the number of disease events has increased significantly and that this trend will continue in the future.³ Disease outbreaks emerging from changes in human demography, increased interaction with wildlife, changes to the environment, and newly evolving drug resistant strains, represent the leading types of emerging diseases. The increasing frequency and regularity with which these outbreaks of dangerous diseases are appearing raises the question about greater accessibility to these biological agents by individuals with malicious intent and their subsequent use for harmful purposes. What role could a naturally occurring disease outbreak play in providing opportunities for a terrorist acquiring a biological agent and using it as a weapon of bioterrorism? While most experts highlight the unlikelihood of such a scenario, the potential is worthy of discussion and dictates the need for enhanced biosecurity policies and practices amidst an outbreak situation, in order to reduce the risk of deliberate theft and diversion of dangerous biological agents.

3. Understanding the biosecurity threat from naturally occurring infectious disease outbreaks is a critical factor in formulating and implementing effective yet practical biosecurity measures, that balance the need for effective biosecurity without over-emphasising the threat. Not all infectious disease outbreaks present biosecurity threats, and the majority of outbreaks remain localised low impact events that do not involve biological agents of bioterrorism concern.⁴ A worldwide study of 1,099 outbreak investigations from 1988 to 1999 by the Centers for Disease Control and Prevention's Epidemic Intelligence Service identified that only 4.0% of the naturally caused outbreaks investigated were as a result of an agent that is also of bioterrorism concern.⁵ To include all naturally occurring disease outbreaks within the scope of biosecurity policies would wrongly overemphasise the threat. The greater biosecurity concern is with disease outbreaks that cause serious widespread illness and death, and that cause societal, economic and political disruptions. In 2002, the World Health Organization described a number of biological agents considered of special concern because of possible use in terrorism (see Box 5.2).⁶ All of these agents cause natural disease in humans, though with differing frequency and consequences. Some of these agents also cause sporadic natural outbreaks, especially in the resource-limited countries of the world. The 2003 outbreak of SARS and the 2014/2015 outbreak of

Ebola haemorrhagic fever in West Africa are additional illustrative examples of natural disease outbreaks of special concern. Outbreaks of drug-resistant disease such as extensively drug resistant tuberculosis (XDR-TB) can also be added to the list, as they pose serious threats to public health and can be very difficult to treat and control.

Box 5.2: Diseases of concern and their natural occurrence (World Health Organization)

Bacterial	
Anthrax	Human cases are most frequent in Africa, the Middle East and in Central and Southern Asia
Brucellosis	Worldwide
Glanders	Rare or absent in most parts of the world
Melioidosis	Prevalent in South-East Asia
Tularaemia	Only rarely transmitted from animals to humans in Central Asia, Europe, Russia, North America and sporadic cases in several countries
Plague	Recent outbreaks in Africa, Asia and South America and sporadic cases in several countries
Q fever	Worldwide
Typhus fever	Endemic foci in parts of Mexico, Central and South America, Central and East Africa and various parts of Asia
Fungal	
Coccidioidomycosis	Worldwide in arid and semi-arid regions
Viral	

Venezuelan equine encephalomyelitis	Endemic in Central and Northern South America
Smallpox	No case confirmed since laboratory-associated outbreak in 1978

4. The degree of suffering and scale of impact demonstrated by these naturally occurring disease outbreaks raises the possibility that terrorists may seek to use these events to their advantage. What is the likelihood of disease agents from natural outbreaks being diverted into the hands of terrorists for malicious use? The logistical challenges and technical hurdles of transforming a natural disease outbreak into a tool of bioterrorism are many. To start with, isolating an agent in its natural environment can be difficult and takes technical knowledge and expertise in microbiology. An analysis by W. Seth Carus (Centre for Counterproliferation Research, US National Defense University) of research on 33 cases of biocrimes and illicit use of biological agents from 1990-2002 by both terrorists and by criminals (those motivated by personal revenge or financial gain objectives) notes only 6 cases of obtaining a pathogen “naturally” by acquiring it from its natural host (e.g. extracting the agent from an infected host or source).⁷ While isolating microorganisms in nature requires specific technical expertise, during a disease outbreak setting there may be greater potential for individuals to easily obtain the biological agent by stealing readily accessible and poorly secured clinical and laboratory samples. The historical record suggests that bioterrorists are generally opportunistic and seek out the most accessible source of pathogens.⁸ Aum Shinrikyo, for example, thought that they could acquire the live Ebola virus by traveling to Zaire during an outbreak in 1992, ostensibly to help Ebola victims.⁹ While unsuccessful, the group’s real intention was likely to obtain virus samples, culture them and use them in biological attacks.

5. The insider threat (i.e. an individual who has been granted legitimate access) presented during a widespread disease outbreak is also a challenge, because of the presence of hundreds of individuals all with access to sources and samples of the biological agent. The potential risks of such individuals exploiting that access deserve attention. Carus noted that 4 of the 33 cases of acquisition of agents for illicit use involved stealing a biological sample, and almost all of the thefts involved people

who had legitimate access to the facilities where the biological agents were present. During an outbreak, local communities are the first to respond, followed by national governments and international organisations. What kind of personnel reliability programme is in place for individuals working in the field? Do they have appropriate knowledge in the biosecurity risks associated with the biological agents they may be handling? Compounding the problem is the need to rapidly scale up human resources in order to bring a spreading outbreak under control. The World Health Organization reports that a shortage of human resources exists in all categories of workers (e.g. healthcare providers, lab workers, burial teams, and logisticians) needed to effectively respond to a disease outbreak in many countries around the world.¹⁰ Initial scaling up of human resources may be focused on acquiring individuals with appropriate skills and training, while proper vetting and background checks of all of these individuals in advance could be challenging, especially for many low resource regions of the world. There are often numerous individuals working tirelessly in the field during an outbreak, and many without adequate salaries. Workers who receive little or no pay may feel aggrieved, resenting the fact that, for example, as local community workers they may be earning less than international aid workers; these individuals may be at risk of diverting biological materials into the wrong hands.

6. It is important to remember that accessing the biological agent is not sufficient. Once the agent is acquired, the individual faces a second and even more technically demanding hurdle of transforming the agent into a weapon of terror. Agents of bioterrorism concern have inherent risk, are dangerous, and are difficult to safely manipulate. If the individual is successful in acquiring the disease agent from an outbreak, they face the challenge of not infecting themselves during the weaponisation process. Because of sloppy laboratory practices, members of the Aum Shinrikyo cult, including cult leader Shoko Asahara, reportedly became infected with Q-fever, a rickettsial disease they were preparing as a biological weapon.¹¹ Additionally, the methods to weaponise a biological agent are not easy, including growing the agent with the desired characteristics and effectively dispersing it. Dissemination methods for highly infectious biological agents, such as the case of the suicide bioterrorist, would have to overcome the challenges of calculating the incubation period properly to ensure the “bomber” is not incapacitated before completing the mission. See Chapters 3 and 4 for further details and case studies

examining the practical barriers to weaponisation that limit what terrorists seeking to cause high-casualty, high-impact events could realistically achieve.

A case study of the 2014/2015 West Africa Ebola outbreak

7. The 2014/2015 outbreak of Ebola haemorrhagic fever in West Africa evolved into the largest, most severe and complex outbreak in the history of the disease. Global health experts faced enormous challenges to bring the epidemic under control, and declared the unprecedented outbreak to be a “public health emergency of international concern”. The Ebola outbreak became epidemic in West Africa in large part because of weak health systems and no reserve capacity to mount an effective response. For the first time in history, an emergency session of the United Nations Security Council was called to address a public health issue, and on 18 September 2014 the Security Council declared the Ebola outbreak a threat to peace and security. Briefing the Security Council members, Dr Margaret Chan, Director-General of the World Health Organization said, “None of us experienced in containing outbreaks has ever seen, in our lifetimes, an emergency on this scale, with this degree of suffering and with this magnitude of cascading consequences.”¹² The World Health Organization’s strategic action plan for Ebola outbreak response called for immediate actions to support affected West African countries, including ensuring that biosecurity measures were in place for handling specimens.¹³

8. The resulting impacts of the 2014/2015 Ebola outbreak spanned well beyond health, stalling development and affecting economies. The World Bank projected possible losses of 32 billion US dollars to the region and commented that, “With a large expansion of the outbreak, and Ebola spreading to other countries in the region, children would lose their providers, households would suffer losses to their income, businesses would lose workers to death, illness, and fear, and industries like mining and agriculture would slow down significantly”.¹⁴

9. In the case of an outbreak that has taken the lives of tens of thousands and devastated economies, could terrorist groups or individuals with malicious intent use the Ebola crisis to their advantage and wreak havoc in other regions of the globe?

This question has been examined by experts who generally agree that, although possible, the formidable challenges of weaponising the virus make it unlikely.¹⁵ The virus is listed as an agent of bioterrorism concern in part because of its high mortality rate, the potential for significant public health and economic impacts, and its ability to cause public panic and social disruption. But acquiring the virus and transforming it into a weapon requires careful skill and resources, and previous attempts to use the virus for bioterror have failed.¹⁶ While it may be unlikely that the West Africa Ebola outbreak could be turned into a deliberate malicious attack, the possibility exists, especially given the nexus of threats in the region: terrorist activity, the increased presence of the virus, and political instability.

10. Given the scope of the recent outbreak, some experts suggest that it would not be difficult to obtain a sufficient sample of the virus to cause harm.¹⁷ Just one to ten virions from an Ebola patient's blood are enough to infect another individual.¹⁸ The huge surge in sample collection, transport, and testing throughout the region leads to increased opportunities for samples to be misplaced, stolen or misused. Response teams are struggling to cope with infection control, biosafety practices and getting results from diagnostic testing as soon as possible. The level of awareness of biosecurity is unlikely to be the primary focus. One case of robbers waylaying a taxi and stealing a cooler of blood samples likely containing Ebola virus was reported in Guinea.¹⁹ The package was being transported by a Red Cross courier, one of nine passengers sharing the taxi, because of a shortage of vehicles in the area. In this case the criminals also stole cellphones and cash and were not specifically targeting the blood samples likely containing Ebola virus. In Liberia, angry protesters raided an Ebola clinic and stole blood-stained mattresses, bedding and medical equipment.²⁰ The potential for mishandling samples of Ebola from outbreaks is not limited to West Africa, but could occur in any country involved in the response, as illustrated by the recent case in the United States where Ebola samples were sent from a high containment laboratory to a laboratory not equipped to securely and safely handle the live Ebola virus.²¹

11. Disease and security experts have speculated about several mechanisms by which the virus, once acquired, could theoretically be used for small-scale attacks. First, Ebola virus could be weaponised by acquiring relatively large quantities, and

inserting them into a small “bomblet” that, once detonated, would spray the virus, potentially infecting people as it landed on them. In this scenario, the virus would not need to be altered in any way to make such a strategy work. However, assuming that a terrorist was able to deliver the virus in this way, sub-optimal conditions could reduce its effectiveness relatively quickly. Unlike anthrax endospores, the Ebola virus is not very hardy and is sensitive to climatic conditions such as exposure to sunlight and extreme temperatures.

12. The second option that has been speculated by security experts would be to recruit individuals for Ebola suicide missions, who would directly infect themselves via a sick person during an outbreak or steal a sample and infect themselves later. Ebola is unlikely to be transmitted by asymptomatic individuals, and such a strategy would hinge on calculating the incubation period properly to ensure the potential terrorist exhibiting symptoms (and thus able to infect others) is not too weak to complete the mission. Given Ebola’s method of transmission (i.e. direct contact with infected bodily fluids), this method of dissemination would not result in widespread illness and death, but given the gruesome nature of the disease, could create significant panic and fears.

13. Another hypothetical scenario involves genetically modifying the virus to enable it to spread more readily, and disseminating it through the air.²² Growing and manipulating the virus safely is virtually impossible to accomplish without the use of a highly sophisticated laboratory and equipment. Even with the use of a relatively adequate laboratory, individuals without specific expertise in handling the agent have a high risk of contracting the disease themselves.

Implementing biosecurity in the context of a widespread disease outbreak

14. While international recommendations for biosecurity measures for laboratories handling biological agents in a laboratory setting are available²³, there are no specific international guidelines that provide clear advice on what biosecurity measures should be implemented by response teams during all stages of controlling an outbreak (i.e.

patient care, specimen collection, field laboratory operations, and burials). With no international consensus, and varying degrees of national biosecurity strategies in place, confusion and jurisdictional issues may arise during an outbreak that crosses borders, with respect to which biosecurity strategy should be executed. Countries have different opinions on which biological agents are of concern during an outbreak, and may have different approaches to biosecurity control strategies in general and during an outbreak response. Response teams made up of local communities, national authorities, regional representatives and international aid organisations may rely on their own level of understanding of what biosecurity measures should be implemented. In many countries, there may be little or no awareness of the biosecurity threats posed by an outbreak response. A recent study in Uganda, a country with a previous history of Ebola outbreaks, revealed inadequate levels of awareness on laboratory biosafety and biosecurity among health and veterinary professionals in the country.²⁴ The authors note a need for raising awareness, training relevant professionals, and formulating measures, policies, regulations and laws to help prevent the misuse of dangerous biological agents and toxins in Uganda.

15. It is clear that steps need to be taken to raise awareness among frontline workers and officials of the benefits of biosecurity, and that a complex and sustained natural disease outbreak creates circumstances in which individuals with malicious intent may have increased access to the virus. Biosecurity measures should be built into the response strategy across the entire spectrum of the outbreak, from patient care to laboratory diagnostics in the field, and clearly communicated to all sectors involved in each step of the response. But, given the complexity of a widespread outbreak response in the field, and with resources likely already stretched, how can biosecurity be effectively implemented on the frontlines? How can we advocate for additional biosecurity measures, without placing an undue burden on response teams struggling to cope with critical infection control and biosafety practices. One possible solution lies in technically sound, locally-relevant and practical measures that balance the need for effective biosecurity, while not overemphasising the threat. Biosecurity measures should be built with local cultures and communities, be creative, be flexible, and be adaptable to the evolving situation during an outbreak.

16. Protecting dangerous pathogens from theft or diversion requires a unique set of measures not typical of traditional security measures. Biological disease agents are present in many locations (e.g. clinics, hospitals, treatment centres, laboratories, ambulances, burial sites) which are often accessible to an ever-changing workforce and the general public. There are no mechanisms to detect the removal of disease agents from these areas and, since they are replicating living organisms, theft of a minute quantity could present a serious threat. Typically, biosecurity practices to reduce this threat would include physical security measures (e.g. locking the entrance to facilities where agents are manipulated, storing pathogens in locked freezers), access control measures (e.g. unique PIN codes for access to facilities, restricting the distribution of keys) and pathogen accountability measures (e.g. maintaining an up-to-date inventory of biological agents on hand). While the challenges associated with implementing these measures during a natural widespread outbreak are many, some simple measures that enhance biosecurity, and which are at the same time complementary to existing outbreak control measures are presented below (Box 5.3).

Box 5.3: Practical biosecurity measures to be taken during a natural disease outbreak

- i. Supervising the transport of infected patients from their homes to the patient care centres.
- ii. Setting up patient isolation areas with restricted access and limiting the number of individuals entering (e.g. by installing a rope or fence barrier around the isolation area, by using a separate building for patients, by using a ward within an existing facility that can be separated from the rest of the healthcare facility, preparing a list of all individuals authorised to enter, using a sign-in sheet when entering the area, stationing a guard at the entrance to the isolation area).
- iii. Moving samples from patient areas to laboratories as soon as possible i.e. with no long-term storage of samples in the patient areas; implementing a “chain of custody” sign-off for samples from the time they are collected from the patient to their receipt at the laboratory; transporting specimens in secure containers, without identifying the disease agent name on the outermost packaging; including the name and contact number of a responsible individual on the

outermost packaging; coordination between patient areas and laboratories, whereby handing-off samples from clinicians to laboratorians occurs only after verification of the individual's identity (i.e. the individual is authorised by the laboratory to receive samples).

- iv. Maintaining 24/7 oversight of mobile field laboratories to ensure samples are not left unattended; ensuring no long term storage of samples in field laboratories.
- v. Extensive disinfection of potentially contaminated materials, linens, soiled surfaces, transport vehicles, patient homes, and the surrounding environment.
- vi. Supervising the disposal and burning of potentially contaminated wastes.
- vii. Oversight of burials and securely sealing remains.
- viii. Reporting any suspicious behaviour or activity in and around patient centre and laboratories.

17. Securing biological materials is highly dependent on the integrity of the individuals who have access to them. As such, another important element to consider in developing a comprehensive biosecurity strategy is the goal of ensuring individuals with access to samples and disease agents are suitable, reliable and do not pose an insider threat. While many countries rely on personnel screening and conducting background checks to achieve this, the presence of hundreds and sometimes thousands of individuals from local communities, national health authorities, and international aid agencies involved in a widespread outbreak makes this approach not necessarily feasible in an outbreak setting. Rapid scaling up of human resources in an effort to control the spread of the outbreak may be in conflict with the need for advance screening of individuals. While individuals working for or volunteering for a UN agency and many international aid agencies, such as the Red Cross and Doctors without Borders, are required to undergo a background check prior to deployment, this is not the case for all workers that may be present in the outbreak zone. While simple approaches such as working in pairs could offer some added measure of security, raising awareness within the outbreak response community to maintain vigilance about biosecurity issues and promoting a culture of responsibility may provide a greater impact. The UN's mission readiness guidelines call upon all UN

workers to embrace all aspects of behaviour of an international civil servant, including such qualities as honesty, truthfulness, impartiality, and incorruptibility.²⁵

18. The need for enhanced biosecurity measures has also been underscored in various international instruments, although typically these have referred to biosecurity and securing dangerous pathogens within the narrower context of diagnostic or research laboratories. While the World Health Organization's strategic action plan for an Ebola outbreak response calls for ensuring that biosafety and biosecurity measures are in place for handling specimens, no further guidance is given on what those measures might be. The World Health Organization's guidance for laboratory diagnosis of Ebola states that staff should be trained in how to collect, store, package and ship specimens, following national/international guidelines, with no mention of biosecurity.²⁶ The World Health Organization's guidance on shipping samples emphasizes the need to preserve the integrity of materials, and facilitate their timely arrival at destination, again with no specific mention of biosecurity (although the guidelines are based on international transport regulations, which likely have considered biosecurity issues in transport).

19. Increasingly, the Biological and Toxin Weapons Convention (BTWC) is being used as a platform for discussing natural disease outbreaks, in addition to deliberately caused outbreaks. States Parties to the BTWC have been addressing biosecurity with the aim of strengthening national implementation of the Convention. States agreed in 2008 on the value of having national authorities define and implement biosecurity measures in accordance with relevant national regulations and policies, and that such measures should be practical, adapted for local needs, and appropriate for the biological agents of concern. Each country is responsible for its own ideas of what such biosecurity measures would entail, and a national compendium of approaches has been provided by 20 countries to the BTWC's Implementation Support Unit²⁷. However, it is not clear the degree to which any of these approaches includes clear guidance and details on what biosecurity measures are mandated in the context of securing pathogens across the entire spectrum of a natural disease outbreak response (i.e. without limiting the focus to laboratories or transportation). At the Seventh Review Conference of the BTWC in 2011, States Parties agreed a programme of work for 2012-2015 that included continued discussion of biosecurity issues. Topics

included addressing capacity-building, through international cooperation, in biosafety and biosecurity, and for detecting, reporting, and responding to outbreaks of infectious disease or biological weapons attack, including in the areas of preparedness, response, and crisis management and mitigation. In 2014, States Parties reiterated the value of considering the lessons learned from natural outbreaks of infectious disease, such as Ebola.

Involving academia & non-governmental organisations in a collaborative outbreak response

20. Building biosecurity strategies and best practices during an outbreak setting requires a multisectoral approach (i.e. integration across the human and animal health, security and environmental sectors) and collaboration among governments, academia, international agencies and local communities (Box 5.4). Many countries of the world do not have sufficient internal resources to respond to and control a widespread outbreak, and lack resilience in their healthcare systems. Regional and international partnerships across these sectors are thus essential. A collaborative approach not only ensures that the combined resources and technical expertise of the different sectors and partners are leveraged during the response, but also avoids inadvertent efforts to implement duplicate separate activities. Briefing the 2008 meeting of the BTWC, Ban Ki-moon, UN Secretary-General, said: “To manage the full spectrum of biological risks, you need a cohesive, coordinated network of activities and resources”.²⁸ In September of 2014, Ban Ki-moon affirmed his commitment to collaboration, and created the Global Ebola Response Coalition (GERC), a diverse group of the most affected countries, bilateral and multilateral donors, non-governmental organisations, academic institutions and UN Agencies, to provide strategic coordination and end the West Africa Ebola outbreak. A key activity of the GERC is developing a shared understanding of the priority needs and mobilising resources which are needed to meet them. As stated by David Nabarro, UN Coordinator for Ebola: “Those of us who have worked in complex situations know that coordination saves lives and improves efficiency.”

Box 5.4: Government engages local students in Mali to control Ebola

Local staff and existing infrastructures were used in innovative ways to control the 2014 Ebola outbreak in Mali. The Government used medical students, with training in epidemiology, to quickly build up teams for aggressive contact tracing. “These people know the country and its culture and will be there, in the countries, long after foreign medical teams leave” remarked Dr. Chan, Director-General, World Health Organization.²⁹

21. It should also be understood that, during an outbreak, policy decisions will likely be made by those with authority based not solely on controlling the outbreak, but on the population’s health and security as a whole and other political considerations. Notwithstanding such political pressures, collectively, the multisectoral response actions to control an outbreak should be based on science and rationality, instead of raising public fears. Naturally occurring disease outbreaks likely play a limited role in providing opportunities for an individual to acquire and use a biological agent as a weapon of terror. Grandstanding by individuals for political gain, implementing a chaotic range of policies, exercising overly excessive caution, and raising the alarm of bioterrorism, offer little assistance in controlling outbreaks of disease. Using election advertisements citing Ebola and the threat of bioterrorism, one US candidate said: “We’ve got an Ebola outbreak, we have bad actors that can come across the border; we need to seal the border and secure it”; and in a 2014 Associated Press poll, voters ranked the threat from ISIS and the threat of Ebola as “extremely or very important.”³⁰

22. There is also general recognition of the enormous value of national and international non-governmental organisations in the control of outbreaks. Non-governmental organisations provide unique support that would not otherwise be available, particularly in reaching low resource areas of the world. Coordination efforts should also build on existing biosecurity capacities and networks at the national, regional and international levels. For example, most regions in the world, including West Africa, have access to professional associations of local biosafety and biosecurity experts who can be called upon for guidance.³¹ National and international multidisciplinary teams preparing for and responding to an outbreak should harness

the power of these individuals, who not only possess biosecurity expertise, but have great knowledge of the local situation and what measures can be effectively applied within the local context. As members of the community, they are perfectly placed to have access to and support from the local population. Local non-governmental organisations are able to respond fast and face few political barriers to participate early on in the response. They can be called upon to deliver a variety of services, from biosecurity awareness-raising among response team members, implementing biosecurity practices regarding the collection and movement of samples, to assisting governments with integrating biosecurity into overall response strategies.

23. When an outbreak is suspected, the World Health Organization recommends the mobilisation of a multi-disciplinary response team to take initial control measures, and that the competencies of each member be defined, in order for each individual to have a precise idea of what needs to be accomplished in the field. The International Federation of Biosafety Associations (IFBA) has defined competencies for biosecurity professionals, with supporting education programs being provided by local biosafety associations worldwide. The level of professional competency in the international biosecurity community is widely divergent: both well-qualified and severely under-qualified individuals are providing advice and guidance on managing biological risks in an outbreak setting. An effective way to reduce this risk is to ensure individuals are assessed as competent through an internationally accepted system for certifying professionals (Box 5.5).

Box 5.5: Professional certification in managing biological risks

In 2014 the International Federation of Biosafety Associations launched a new professional certification programme for individuals to demonstrate competencies in biorisk management, biosecurity, biological containment facilities and other technical disciplines related to the management of biological risks.³² Individuals are encouraged to enrol in this distinctive programme and become professionally certified as having demonstrated competency in biosecurity.



Conclusion

24. While not all natural disease outbreaks are caused by an agent of bioterrorism concern, the increasing frequency and regularity with which outbreaks of dangerous diseases are appearing raises the question about greater accessibility to these biological agents by individuals with malicious intent and their subsequent use for harmful purposes. There is an increase in the scale and complexity of natural outbreaks, and the 2014/2015 outbreak of Ebola in West Africa provides a recent example of an opportunity for individuals with malicious intentions to exploit the circumstances of an outbreak and access the virus. Most experts highlight the unlikelihood of a bioterrorist attack using Ebola virus; however, this should not prevent the implementation of biosecurity policies and practices amidst an outbreak situation. To be effective, biosecurity practices during an outbreak should be locally-relevant, practical, adaptable to changing outbreak circumstances, and not strain already weakened response teams, systems and resources. They should build upon, and be complementary to, ongoing outbreak response activities being implemented to control the outbreak. Biosecurity measures should also be clearly written into international and national response strategies for controlling natural disease outbreaks beyond the laboratory context, and integrated within national regulatory frameworks. Finally, multi-sectoral approaches, collaboration and networking are of paramount importance, and should include competent biosecurity professionals working together with local communities. Individuals are encouraged to become internationally certified in biorisk management and biosecurity through the new programme offered by the IFBA.

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Chapter 6: The BTWC: structure and development

Jez Littlewood

Key learning objectives

- i. Understand the essential aspects of the Biological and Toxin Weapons Convention and its role in preventing the deliberate use of disease as a weapon;
- ii. Develop an appreciation of the role of different actors (States, Non-State, Individuals) and events in the evolution of the Convention over 40 years;
- iii. Understand that, although the Convention has both strengths and weaknesses, it remains robust in the face of challenges to the norm against disease as a weapon.

Introduction

1. The Biological and Toxin Weapons Convention (BTWC) entered into force on March 26, 1975. It is now over 40 years old. Over that 40 year period the world has changed in dramatic ways in the areas of international politics and international security. For example: the Cold War between the United States and the Soviet Union and their allies ended; change has occurred in health and welfare, with dramatic reductions in infant mortality, as well as provision of basic healthcare to billions of people; in trade and economics, globalisation has had a range of impacts, not least in terms of significant increases in trade between states; and, scientific and technological developments across many scientific fields, including the life sciences and computer sciences, have seen the emergence of scientific disciplines that have witnessed ground breaking developments, such as those that have resulted in the emergence of bioinformatics.

2. Against this background of fundamental change there are also remarkable continuities in the contemporary world. States remain the dominant actors in international relations and global politics – though by no means the sole or always

most powerful actors – and states still order and influence the lives of most of the seven billion people living on the planet. Of equal note, the norm against the use of poison in warfare remains robust, despite occasional breaches of the norm and violations of international law. No state actively promotes or boasts of any biological weapons programme, and very few acknowledge their possession of either chemical or biological weapons. The 1925 Geneva Protocol, which prohibits the use of chemical and biological weapons in warfare, is considered to be binding on all states, regardless of whether or not they are members (States Parties) to the Protocol. Aside from occasional use of biological weapons by terrorist groups (see Chapter 4), the suspected use of toxins as assassination weapons, and indications of secret state programmes related to offensive biological weapons, the norm against biological weapons, and international law prohibiting the use of these weapons (the Geneva Protocol) and the development, production and stockpiling of biological and toxin weapons (the Biological and Toxin Weapons Convention) has remained robust and able to withstand different crises over the last four decades.¹

3. Thus, when the BTWC entered into force, it was one of two international mechanisms that aimed to prohibit and prevent the use of disease as a weapon. As Millett observed, the BTWC “is a crucial keystone among numerous instruments and initiatives in our collective defences against poisoning and deliberate disease.”² As Graham Pearson outlines in Chapter 7, the Convention is one of many laws, mechanisms, and instruments in place within what Pearson refers to as a ‘Web of Prevention’. How the Convention has evolved, from being the principal bulwark against biological and toxin weapons in 1975, to being the foundation of a complex, layered, web of prevention against the background of such dramatic changes in politics, trade and scientific endeavour, is the subject of this chapter. It outlines briefly the history of biological weapons use and development within States, the origins and structure of the BTWC, and the evolution of the Convention over time, based on actions by its member states and civil society groups, and in response to events in the wider world.

The Biological and Toxin Weapons Convention

4. The taboo against poison as a weapon has deep roots across history and different cultures, including religious cultures and beliefs. It was not until the second half of the nineteenth century that the normative constraints against the use of poison became codified, institutionalised and embedded into international agreements.³

5. Biological weapons did not feature prominently in World War One (WWI), although sabotage efforts involving biological weapons have been documented.⁴ Within Europe neither chemical nor biological weapons were used extensively in World War Two (WWII), despite preparations for such use by both Allied and Axis powers. In North East Asia, however, in the inter-war period Japan had employed both chemical and biological weapons against China.⁵ Subsequently, the United States, the United Kingdom, and the former Soviet Union developed offensive biological weapons in what were large-scale mid-20th Century programmes.⁶

6. The first half of the twentieth century therefore saw very limited use of biological weapons, and no use was decisive in a tactical or strategic sense. The important developments in respect of state interest in this form of warfare were related to, and strongly influenced by, the perceived tactical and strategic advantages of biological weapons in warfare flowing from greater understanding of science and technology, as well as assumptions that other states would pursue biological weapons because of the perceived advantages in warfare. In essence, scientific and technological innovation became militarised in an environment of Great Power competition.

7. Following the use of nuclear weapons against Japan in 1945, the international community moved to limit the development and use of weapons of mass destruction by states. The objective of general and complete disarmament remained simply that – an objective – but arms control agreements related to nuclear weapons in the early-to-late 1960s culminated in the Nuclear Non-Proliferation Treaty (NPT). In the United Nations the Committee on Disarmament turned its attention to chemical and biological weapons in 1968-69.

8. A convergence of various events and interests in the years 1969 to 1971 resulted in the BTWC. While a number of states possessed chemical weapons at the time, few were believed to have biological weapons programmes. Moreover, verification of chemical weapons disarmament, a requirement for the United States because of the known existence of chemical weapons arsenals, was rejected by the Soviet Union, thus making any agreement on chemical weapons unlikely. However, with the United States under political and moral pressure related to its use of defoliants in the Vietnam War – namely Agent Orange and other herbicides – and concern among the public and some policymakers about the safety of the United States’ chemical and biological weapons programmes (following an accident that resulted in the death of a large number of sheep), the United States accepted a proposal from the United Kingdom to negotiate a biological weapons treaty, leaving chemical weapons off the agenda to be dealt with in future negotiations. In addition, a high-level policy review in the United States led to the unilateral renunciation of biological and toxin weapons by the United States in 1971.⁷ Finally, following that unilateral decision, the Soviet Union accepted the proposal to separate chemical and biological weapons controls into two different treaties (Conventions).

9. The cumulative impact of these changes resulted in the Soviet Union and the United States circulating identical draft treaties in the summer of 1971 in a ‘take-it-or-leave-it’ deal to the other states of the Conference on Disarmament. Despite some concerns about the absence of verification provisions within the Convention, the draft text was accepted and the Biological and Toxin Weapons Convention was opened for signature in 1972.⁸

10. The text was modelled on the Nuclear Non-Proliferation Treaty. It contained obligations for disarmament, non-proliferation, national implementation, cooperation and consultation mechanisms, investigation procedures for alleged violation of the BTWC, assistance provisions in the event of use of such weapons, peaceful cooperation undertakings, and a periodic review of implementation of the Convention. The basic commitments are outlined in Table 6.1.

Table 6.1: Key provisions of the Biological and Toxin Weapons Convention.⁹

Article	Provision
Article I	Never under any circumstances to acquire or retain biological weapons
Article II	To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining
Article III	Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons
Article IV	To take any national measures necessary to implement the provisions of the BTWC domestically
Article V	To consult bilaterally and multilaterally to solve any problems with the implementation of the BTWC
Article VI	To request the UN Security Council to investigate alleged breaches of the BTWC and to comply with its subsequent decisions
Article VII	To assist States which have been exposed to a danger as a result of a violation of the BTWC
Article X	To do all of the above in a way that encourages the peaceful uses of biological science and technology

11. The historical record indicates that the negotiations were not too difficult: while a significant number of states preferred a chemical and biological weapons Convention, the deal between the United States and the Soviet Union rendered such preferences irrelevant. Neither the United States nor the Soviet Union envisaged a requirement for verification provisions, given the difficulty of addressing the dual-use dilemma and the disagreement over on-site inspections of facilities. As a result, the Convention's key weakness at the time of its negotiation was the lack of detailed and agreed provisions to implement its legal obligations and, through such provisions, ensure compliance with its obligations. States had to trust one another.

12. This key weakness remains. However, over time States have adopted additional understandings and developed other mechanisms within the Convention, as well as outside of it, to mitigate some of these issues and concerns. How, and why, States

have undertaken those measures is at the heart of the evolution and development of the Convention over the last forty years.

Development of the Convention

13. Within the BTWC is a procedural undertaking under Article XII for a review of the operation of the Convention. That procedure – the Review Conference – has evolved into one of the most significant mechanisms available to all States Parties to reaffirm, as per the Preamble of the Convention, that States Parties remain determined “for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons.”¹⁰ Article XII envisaged a conference of States Parties five years after entry into force, that is no later than 1980, “to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention...are being realised. Such a review shall take into account any new scientific and technological developments relevant to the Convention.”¹¹ The first Review Conference was held in 1980. Among other things, it was agreed by the Review Conference that a second review would be undertaken within six years and, since that time, each Review Conference has mandated a further review at approximately five-yearly intervals. As a result, seven Review Conferences have been held to date in 1980, 1986, 1991, 1996, 2001-02, 2006, 2011, and the eighth such Conference is scheduled for 2016.

14. This procedure has allowed States Parties to discuss and address many different challenges to biological disarmament. The importance of that provision was outlined by Sims and Littlewood in 2011:¹²

the [BTWC] is about biological disarmament and removing biological and toxin weapons from state arsenals. In many respects that basic objective has been achieved, but disarmament is a process, and the problem of biological weapons predominantly manifests itself as the management of the dual-use problem. To be more specific, the [BTWC] is not about the destruction of existing stockpiles of weapons: it is about ensuring that states do not develop new arsenals for the future. The capability to develop biological weapons in terms of pathogens, toxins, materials, equipment, and knowledge exists in

many states, and the [BTWC] is primarily concerned with ensuring that states do not use such capabilities for offensive programs.

15. How do States Parties “ensure that states do not use such capabilities for offensive programs’? Or, to be more specific, what role does a procedure – the Review Conference – play in the evolution of the BTWC? In simple terms the review allows States Parties to respond to events and incidents and agree upon responses to strengthen the Convention. At a Review Conference States Parties review the BTWC in its entirety, that is to say all fifteen Articles of the text.

16. For example, under Article XV, English, Russian, French, Spanish and Chinese texts of the BTWC that are authentic are accepted as authoritative and correct texts of the Convention. Thus, the Convention can be found in each of the five languages noted above and identified in Article XV. Since 1975, Arabic has become an accepted and recognised language at the United Nations. To acknowledge Arabic as an official language and incorporate that change in practice at the United Nations, in 2006 (Sixth Review Conference) the States Parties agreed by consensus “that as well as the five languages listed in this Article, Arabic shall be considered an official language for the purposes of any meetings of the States Parties and other formal communications concerning the operation of the Convention.” This agreement does not formally change, or amend, the actual legal text of the BTWC. It does, however, change the practice and expectations of States Parties, because the consensus decision to recognise Arabic as an official language is a politically binding agreement among, and between, all States Parties. This type of change – not legal *per se* in terms of a formal amendment of the text of the BTWC – is considered binding on all states. It is what has become known as an ‘Additional Understanding’ or ‘Additional Agreement’.

17. As the background documentation for the Seventh Review Conference (2011) outlines:¹³ “an ‘additional agreement’ is one which: (a) interprets, defines or elaborates the meaning or scope of a provision of the Convention; or (b) provides instructions, guidelines or recommendations on how a provision should be implemented.”

18. All of the above is about procedure, rather than substance. However, its purpose is to note and draw attention to a procedure that has evolved into a very important practice that has substantive implications: namely, States Parties can agree to alter how they implement and interpret the fifteen Articles of the Convention under two conditions. Condition one is where such agreements can be reached; condition two is how such agreements are adopted. They can reach agreements at only one place, a Review Conference, and only when there is consensus among all States Parties at the Review Conference.

19. That consensus, and any additional agreements, is contained in the Final Declaration of any, and each, Review Conference. In essence, it is a procedure that allows States Parties to maintain the BTWC in accordance with its original Article XII requirement “to assure that the purposes of the Convention, and its preamble, are being realised.” The importance of this was elaborated in 1990. Charles Flowerree, an experienced United States diplomat, noted that arms control agreements need procedures and mechanisms that allow States Parties to cope with both extraordinary events and more routine issues related to compliance, including changes in international conditions: to resolve ambiguities; to deal with new scientific and technological developments; to interpret treaty language over time; and to develop implementation procedures.¹⁴ Over time, this approach has allowed implementation of the Convention to evolve and new politically binding commitments to be agreed, developed, and implemented by States Parties. Nine examples of some key additional agreements are listed in Table 6.2. These examples serve to illustrate the importance of this procedure and the scope of its use related to a wide variety of Articles under the Convention. However, it should be noted that, as of 2012 and implementation of the Final Declaration of the Seventh Review Conference, there are over 100 additional understandings in place among States Parties.¹⁵

Table 6.2: Examples of Additional Agreements under the Biological and Toxin Weapons Convention.

Year	Additional Agreement	Implication
1980	Article V: development of procedures on Consultation and Cooperation.	Empowered states to call a meeting of experts to address any challenges to implementation of the Convention.

1986	Article I: reaffirmed that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production.	Recognition and confirmation by States Parties that scientific developments fall under the scope of the BTWC and that the Convention remains comprehensive in its scope and implementation.
1986	Confidence Building Measures	The development of formal and annual information sharing in specific areas between States Parties.
1991	Article IV: education and awareness	Urged the inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol, thus contributing to education of scientists and professionals.
1996	Article I: On use of biological weapons	Reaffirmed that the use by States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I.
2006	Article VI: Investigation of alleged use of biological and/or toxin weapons.	Invited the United Nations Security Council to consider immediately any allegations and to initiate any measures it considers necessary for the investigation of the complaint of alleged use. This includes the United Nations Secretary General's investigation mechanism, which is external to the BTWC.
2006	Article X: information sharing on	Encouraged States Parties to provide

	implementation of the Article.	appropriate information on how Article X is implemented, and requested the United Nations to collate such information for States Parties
2011	Article VII. Assistance in the event of use of biological weapons.	Noted States Parties were willing to provide or support assistance when a State Party has been exposed to danger or damage as a result of the use of bacteriological (biological) agents and toxins as weapons by anyone other than a State Party, i.e. a non-State Party, terrorist group etc.

20. In practice, these additional agreements keep the BTWC up-to-date and allow States Parties to underscore that, regardless of the developments in science, or international security, or in other areas, the prohibition on the development, production, stockpiling, acquisition, retention, or use of biological or toxin weapons remains in force and is not circumvented by events or changes in practice. The Convention and its core obligations are, in effect, still valid, despite scientific and technological developments that have emerged since 1975. Over time, what changes is not the text of the Convention, but implementation of it by States Parties by “a process of cumulative diplomacy and accretion” whereby “each Review Conference built on its predecessor.”¹⁶ As Sims observes, States Parties have used the Review Conferences as a means to develop a “process of reinforcement to remedy perceived weaknesses.”¹⁷

21. Nicholas Sims has characterised this evolution as the emergence of different regimes within the Convention; namely, a regime of compliance, a regime of development, and a regime of permanence, with each regime evolving somewhat independently from the others and all at different paces, yet all overlapping with each other.¹⁸ The regime of compliance is the broadest in scope, covering the core obligations of disarmament (Article I); non-proliferation (Article III); national implementation measures to give effect, or substance, to the obligations and

requirements of the BTWC (Article IV); consultation and cooperation mechanisms to address any concerns about the purpose and the implementation of the Convention (Article V); investigation procedures to address alleged use of biological and toxin weapons (Article VI); and assistance in the event of an attack (Article VII). The core of the regime of compliance is contained within the additional agreements reached at successive Review Conferences.

22. In addition, four other measures and activities have attempted to expand and enhance the regime of compliance. These are the Annual Information Exchange (also known as the Confidence Building Measures); the scientific and technical study of verification undertaken between 1992 and 1993 (generally known as the Verification Experts Group); the negotiations on the Protocol to the BTWC undertaken between 1995 and 2001 (generally known as the Ad Hoc Group and/or the Verification Protocol negotiations); and the Meetings of Experts and Meetings of States Parties held under three intersessional processes between Review Conferences since 2002.

23. The Confidence Building Measures, adopted in 1986 at the Second Review Conference and expanded at the Third Review Conference (1991), encourage States Parties to share information with each other on facilities, activities, and events that are deemed to be highly relevant to the Convention (see Table 6.3). The information sharing was intended to allow States Parties to provide detail and context on activities and events of direct relevance to the Convention: for example, exchange of data, including the name, location, and a general description of activities undertaken at research centres and laboratories with very high national or international safety standards, e.g. Maximum Biological Containment Laboratories.

Table 6.3: Confidence-Building Measures adopted by States Parties.

Year	Measure
1986	CBM A: Part 1: Exchange of data on research centres and laboratories Part 2: Exchange of information on national biological defence research and development programmes
1986	CBM B: Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

1986	CBM C: Encouragement of publication of results and promotion of use of knowledge
1986	CBM D: Active promotion of contact between scientists engaged in research directly related to the Convention
1991	CBM E: Declaration of legislation, regulations and other measures
1991	CBM F: Declaration of past activities in offensive and/or defensive biological research and development programmes
1991	CBM G: Declaration of vaccine production facilities

24. The annual information exchange proved to be much less successful than proponents envisaged, because few States Parties submitted returns on a regular basis.¹⁹ Despite continued efforts to improve both the submission rate and the quality of the information within the Confidence Building Measures, they remain only of limited usefulness. This is not to claim they are without any value or purpose, but in the thirty year period since they were first agreed, they have failed to keep pace with the globalisation of the life sciences, and States Parties have never, collectively, assessed the information submitted by other States with respect to its accuracy, completeness, or relevance.

25. The Ad Hoc Group of Governmental Experts to identify and examine potential verification measures from a scientific and technical standpoint was established in 1991. With the Cold War over and negotiations on the Chemical Weapons Convention close to completion, some States Parties to the BTWC began pushing for a verification agreement that was as broad and deep as that emerging under the Chemical Weapons Convention. That is to say, formal legally-binding declarations, routine inspections of facilities declared, investigation of alleged use and non-compliance activities, and an international organisation to oversee the new verification regime. Political disputes between States Parties prevented agreement on the opening of negotiations, and the compromise was a technical study of the possibilities of verification. This verification experts group was established at the Third Review Conference. The expert group reported in late 1993 and, in a complex report, essentially concluded that some measures in combination with each other would contribute to strengthening the Convention. A Special Conference in 1994

considered the report and established an Ad Hoc Group to develop measures and procedures for all aspects of the Convention, in order to strengthen its effectiveness and enhance confidence in compliance with the undertakings of States Parties. This was the mandate to negotiate a Protocol to the BTWC.

26. The Ad Hoc Group convened in 1995 and at the Fourth Review Conference (1996) it was encouraged to speed up its work. Between 1995 and the summer of 2001 the Ad Hoc Group met 24 times. The negotiations, covering all the key Articles of the Convention, were difficult and States Parties could not agree on many key features of the Protocol. By 2001 the text of the draft Protocol was contained in one single document, but in July 2001 the United States informed other States Parties that it could not accept the proposed text, and that it viewed the effort as fundamentally flawed. In effect, the United States prevented the continuation of the negotiations, though it was not the only State Party that had concerns about the scope and usefulness of the Protocol.²⁰

27. The collapse of the Ad Hoc Group negotiations in the summer of 2001 divided States Parties, and the Fifth Review Conference in late 2001 collapsed into acrimony and had to be suspended.²¹ When it reconvened in late 2002 States Parties adopted a programme of work that has become known as the “intersessional process”, whereby meetings of experts are held in the summer of each year and annual meetings of States Parties take place in December of each year. Each year focuses on different, specific topics, as determined by the Review Conference. Thus, in 2002, the work programme for 2003 to 2005 was devised; in 2006 (Sixth Review Conference), the work programme for 2007 to 2010 was devised; and in 2011 (Seventh Review Conference) the programme for 2012 to 2015 was agreed.

28. The Convention, however, does not exist in a vacuum. Its States Parties have generally proven to be skilled in reacting to changes in the global political and scientific arenas, and have instituted incremental measures, such as the additional agreements noted above. But why and how such incremental adaptations have occurred can be explained only by an understanding of events and how they affect the interaction of many different aspects of the norm against poison – in this case biological and toxin – and the political, legal, scientific, and security perspectives and

perceptions of states and other actors. That is to say, the intersection of norms, politics, science, law and war. For example, the attacks on the United States on September 11, 2001 changed the context of discussions within the Convention: concerns about terrorist interest in biological and toxin weapons became as important as concerns about the interests of States. In a similar manner, as indicated above, the completion of the negotiations on the Chemical Weapons Convention in the early 1990s resulted in many States supporting the development of a very similar agreement for the BTWC, which in turn led to the Verification Protocol negotiations. At an even earlier stage of the Convention's life, the unusual outbreak of anthrax in the Soviet Union in 1979 gave rise to the Confidence Building Measures adopted in 1986. Some key events outside the Convention and their impact on the agreement are noted in Table 6.4.

Table 6.4: Examples of events, incidents, and developments and their impact on the Biological and Toxin Weapons Convention.

Year	Event, Incident, Development	Impact on Convention
1975	Asilomar conference on Recombinant DNA	Scientific community demonstrates awareness of the implications for science and technology and for public safety of technological breakthroughs. Resulted in heightened awareness by States Parties of implications of science and technology in the context of Review Conferences.
1979-80	Unusual outbreak of disease: anthrax in Sverdlovsk (Soviet Union)	Gave rise to suspicions about compliance of Soviet Union with the Convention.
1989-91	End of Cold War	Reduced tensions between United States and Soviet Union. Created more propitious climate for strengthening the Convention.
1991-98	United Nations Special Commission (UNSCOM)	Enforced disarmament of Iraq, and uncovered biological weapons programme in Iraq. Tested inspection procedures under

		discussion by Ad Hoc Group
1993	Chemical Weapons Convention	Completion of Chemical Weapons Convention provided impetus for negotiation of a verification agreement for the BTWC.
1995	Aum Shinrikyo uses sarin on Tokyo subway	Threat of terrorist use of chemical and biological weapons becomes a significant concern. Reflected in later Review Conferences.
2001	September 11, 2001 attacks on United States	Terrorism becomes a national security priority of United States and others. National implementation (Article IV) of Convention becomes a priority under first intersessional process.
2001	Anthrax letters, United States	Heightens concerns about biological terrorism; impetus for national implementation measures.
2004	United Nations Security Council Resolution 1540 (2004)	Requires states to prevent the acquisition of weapons of mass destruction by non-state actors.
2007	World Health Organization International Health Regulations enter into force	Mandatory reporting of specified outbreaks of disease. Outbreak of disease reporting acknowledged as important information for BTWC.

A science, and scientist-activist, perspective on the development of the Convention

29. Neither States nor events are the only influential elements in the evolution of the Convention. Individual scientists and scientific communities have also played an influential role in the structure and evolution of the Convention over time. Daniel Feakes provides an overview of this development for both chemical and biological weapons²² and, like others, notes the existence of an epistemic community that can be defined as, “a network of professionals with recognised expertise and competence

in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area”²³. Four examples illustrate the role that scientists and professional communities have played in the Convention to date.

30. First, as noted above, the United States unilaterally renounced biological weapons prior to the negotiation of the Convention. The High-Level Review by the United States at the national level involved a prominent scientist, Matthew Meselson (see Chapter 3): Tucker notes that Meselson was ‘instrumental’ in persuading senior United States officials to undertake a study to examine the scientific aspects of chemical and biological weapons and, later on, to study toxins and whether or not they should be included within the unilateral disarmament of the United States.²⁴ Second, contemporaneously, and ever since, the Pugwash Movement has also played a major role in the evolution of the Convention under its Chemical and Biological Weapons Study Group²⁵ as the dominant epistemic community. As Feakes notes, “Assessing the influence of Pugwash in [chemical-biological] disarmament is not easy due primarily to a lack of documentation. It chiefly resides in the continuity of its involvement, the informal nature of its workshops, and the originality of its policy research. Between 1959 and 1998, 645 people from 46 countries had participated in Pugwash activity in this field.”²⁶ A third example is the emergence of a global scientific community that has reviewed scientific and technological developments and assessed their implications for the Convention; this is the InterAcademy Panel (Chapter 10) created in 2004, that has worked extensively over the last decade to raise awareness of both the benefits and dangers of science among individuals, professional associations, diplomats, and national governments.²⁷

31. Finally, examples of scientists undertaking activity across a range of actions can be found throughout the history of the BTWC. Feakes identifies a wealth of examples, but for the purpose of this chapter it is sufficient to note that such actions cover the seven roles Albin identified, namely: problem definition; agenda-setting and goal setting; enforcement of principles and norms; provision of information and expertise; public advocacy and mobilisation; lobbying; direct participation in the formulation of international agreements; and monitoring and other assistance with compliance.²⁸ Over time, this involvement with the Convention and interaction with States Parties at Review Conferences and other meetings of States Parties, at the national level, and

within professional associations of scientists, has become deeper and wider; it is likely to be ever more important as the twenty-first century progresses.

Conclusion: Development and evolution in context

32. The BTWC has sometimes been considered as a weak and ineffectual treaty; its brevity (four pages) and its lack of formal, structured, compliance and verification provisions may be considered a weakness. However, with over forty years of implementation history to its credit, it is evident that the Convention, its States Parties, and scientists themselves, have managed to come together at crucial times to reinforce the norm against the use of disease as a weapon, and to enhance the implementation of the Convention to ensure it remains relevant, valid, and robust in the face of scientific developments, changes in international security, and challenges to the norm and the Convention itself. The evolution of the Convention, documented in brief above, demonstrates a robustness and flexibility that has allowed States Parties to ensure over time that, through their actions, they remain determined “for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons.” The BTWC is not perfect; its implementation universally is not complete; and the actions of its States Parties are not above criticism. However, it remains a significant bulwark against the use of disease as a weapon of warfare that cannot be easily circumvented or ignored.

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³ J.P. Zanders, ‘International Norms Against Chemical and Biological Warfare: An Ambiguous Legacy’ *Journal of Conflict & Security Law*, 8:2 (2003), pp.391-410.

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⁹ Table 6.1 is reproduced from the United Nations Office at Geneva (UNOG) website on Biological Weapons: [http://www.unog.ch/80256EE600585943/\(httpPages\)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/04FBBDD6315AC720C1257180004B1B2F?OpenDocument) (accessed 3 April 2015).

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¹¹ Ibid.

¹² Nicholas A. Sims and Jez Littlewood, 'Ambitious Incrementalism', *The Nonproliferation Review*, 18:3 (2011), p.504.

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¹⁵ United Nations, 2011, op. cit.

¹⁶ Nicholas A. Sims, 2001, op cit., p.18.

¹⁷ Ibid., p.17.

¹⁸ Ibid., p.2.

¹⁹ Filippa Lentzos, 'Strengthening the BWC confidence-building measures: Toward a cycle of engagement', *Bulletin of the Atomic Scientists*, 67:3 (2011), pp.26-33.

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Chapter 7: The idea of a web of prevention

Graham S. Pearson

Key learning objectives

- i. Understand the concept of the web of prevention and its key elements;
- ii. Appreciate that such a web is an integrated and comprehensive approach;
- iii. View each of the elements of the web as complementary and mutually reinforcing;
- iv. Understand that the web of prevention is an effective counter to the threat of biological weapons, whether posed by States, non-State actors or terrorists.

Introduction

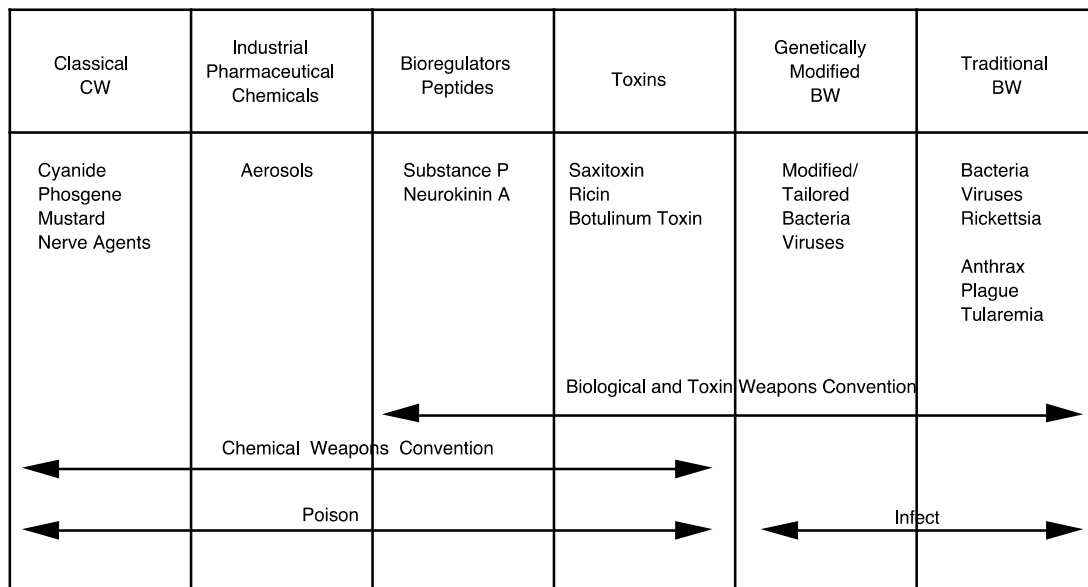
1. The idea of a web of deterrence was first proposed in the early 1990s,¹ when it was evident that the way ahead to counter biological and toxin weapons was through a web of measures, comprising several complementary elements:

- a. effective protective measures that reduce the range of materials that can be used by an aggressor effectively, and also reduce the military utility of biological weapons;
- b. effective arms control agreements, so that such weapons are comprehensively prohibited, and a potential aggressor cannot have any certainty that his programme will not be detected and recognised;
- c. export controls and monitoring, to increase the difficulties of acquiring biological warfare agents or the necessary technology for their production; and
- d. a political commitment to react vigorously with a range of national and international responses – including the possibility of an armed response – if a State is found to be acquiring biological weapons or has gone so far as to use them.

The basic understanding was that, although no single element could suffice on its own, all four elements integrated together would be effective.

2. The web of deterrence came from the growing appreciation in the early 1990s that, for effective protection against chemical and biological weapons, consideration needed to be given to measures that would be effective in countering the CBW spectrum (Fig. 7.1), which extended from classical chemical weapons such as cyanide and phosgene; through industrial or pharmaceutical chemicals to what were then known as ‘mid-spectrum’ agents such as bioregulators and peptides; and then to toxins, to genetically modified biological weapons and to biological weapons.

Figure 7.1: The CBW (Chemical Biological Weapons) Spectrum.



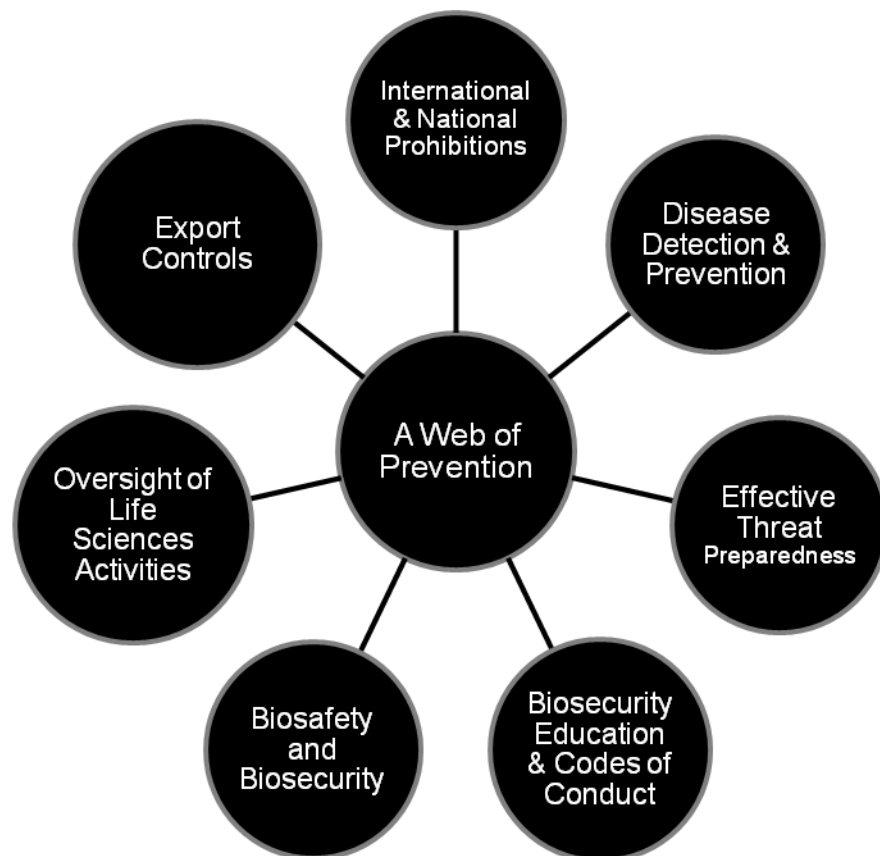
3. The CBW spectrum usefully underlined the fact that there is an overlap between the materials prohibited by the Chemical Weapons Convention², which entered into force in 1997, and those prohibited by the BTWC³, which entered into force in 1975. These two Conventions, together with the 1925 Geneva Protocol⁴ for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, which entered into force in 1928, totally prohibit the development, production, stockpiling and use of any such weapons.

4. The web of deterrence over the subsequent decade developed into a web of reassurance, with similar but broader elements:

- a. a strong international and national prohibition regime, reinforcing the norm that all biological weapons are totally prohibited (see Chapter 12 and Chapter 13 on the role of national and international law enforcement agencies);
- b. broad international and national controls on the handling, storage, use and transfer of dangerous pathogens and toxins;
- c. preparedness, including both active and passive protective measures, and response plans that have been exercised; and
- d. determined national and international response to any use or threat of use of biological weapons, ranging from diplomatic sanctions through to armed intervention.

5. This web also became known as a “web of prevention” (Fig. 7.2) – an integrated and comprehensive approach, in which all of the elements are complementary and reinforce each other, to create an effective counter to the threat of biological weapons, whether posed by states, non-state actors or other entities.

Figure 7.2: Web of Prevention.



6. In this chapter, consideration is given to all elements of the web of prevention, demonstrating how strengthening each of the elements brings benefits to all states and to those who live in them.

A strong international and national prohibitions regime

7. The prohibition regime is shown in Figure 7.3.

Figure 7.3: The prohibition regime.



Biological and toxin weapons are totally prohibited by Article I (see Box 7.1) of the BTWC, which entered into force in 1975.

Box 7.1: Article I of the BTWC.

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

(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.

The States Parties have agreed extended understandings of these prohibitions in the Final Declarations of the Review Conferences held at five year intervals. At the Seventh Review Conference in 2011⁵, the Final Declaration (see Box 7.2) made it clear – note added emphasis – that the prohibition in Article I of the Convention is all embracing.

Box 7.2: Article I Final - Declaration of the Seventh Review Conference in 2011.

1. The Conference reaffirms the importance of Article I, as it defines the scope of the Convention. The Conference declares that the Convention is comprehensive in its scope and that all naturally or artificially created or altered microbial and other biological agents and toxins, as well as their components, regardless of their origin and method of production and whether they affect humans, animals or plants, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, are unequivocally covered by Article I. (Emphasis added)

8. The requirement for national implementation of the prohibitions in the BTWC is set out in Article IV (see Box 7.3).

Box 7.3: Article IV of the BTWC.

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 (Emphasis added)

At the Seventh Review Conference in 2011 the Final Declaration (see Box 7.4) underlined the importance of implementation of Article IV, as well as noting the importance of training and education programmes for those engaged in the life sciences.

Box 7.4: Article IV - Final Declaration of the Seventh Review Conference in 2011.

11. The Conference reaffirms the commitment of States Parties to take the necessary national measures under this Article. The Conference also reaffirms that the enactment and implementation of necessary national measures under this Article, in accordance with their constitutional processes, would strengthen the effectiveness of the Convention. In this context, the Conference calls upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to:

(a) 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, equipment and means of delivery as specified in Article I of the Convention;

(b) 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;

(c) ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorised access to and removal of such agents or toxins.

12. The Conference welcomes those measures taken by States Parties in this regard, and reiterates its call to any State Party that has not yet taken any necessary measures, to do so without delay. (Emphasis added)

9. As of October 2015, there are 173 States Parties to the BTWC, and nine States are signatories but have not yet become full members. 14 States have neither signed nor ratified the Convention: Angola, Chad, Comoros, Djibouti, Eritrea, Guinea, Israel, Kiribati, Micronesia (Federated States of), Namibia, Niue, Samoa, South Sudan, and Tuvalu.

United Nations Security Council Resolution 1540 (2004)

10. The prohibitions and obligations contained in the BTWC were further underlined by the Security Council, which adopted Resolution 1540 (2004)⁶ which in its preamble states that:

The Security Council

Affirming its support for the multilateral treaties whose aim is to eliminate or prevent the proliferation of nuclear, chemical or biological weapons and the importance for all States Parties to these treaties to implement them fully in order to promote international stability, (Emphasis added)

It goes on to require all States, whether or not States Parties to the multilateral treaties, to take steps to achieve that goal. It also established a Committee to report to the Security Council on the implementation of the Resolution. This Committee has produced several reports and has provided a number of useful website pages providing the following information:

- a. All States to present to the Committee a first report, not later than six months from the adoption of Resolution 1540 (2004), i.e. 28 October 2004, on steps they have taken or intend to take to implement this resolution; these National Reports are available⁷;
- b. States are also encouraged to prepare on a voluntary basis summary action plans, mapping out their priorities and plans for implementing the key provisions of Resolution 1540 (2004), and to submit those plans to the 1540 Committee⁸;

- c. Since its adoption in early 2005, the 1540 Matrix⁹ has functioned as the primary method used by the 1540 Committee to organise information about implementation of UN SCR 1540 (2004) by Member States;
- d. A legislative database¹⁰ has been developed by the 1540 Committee for the purpose of providing additional information on the national implementation of regulations and measures related to the Resolution.

Whilst these websites provide a useful insight, it is evident that much still needs to be done in regard to biological weapons, as reported in the last comprehensive review by the 1540 Committee carried out in 2011.¹¹

11. The adoption of UN SCR 1540 (2004) and its continuing implementation provide an overarching and comprehensive reinforcement of the efforts to prohibit biological weapons. Recent developments, for example, in the Middle East, can be followed in articles published in an electronic journal called 1540 Compass.¹² A useful example of such an article covers biosecurity developments in Middle East and North Africa (MENA) countries.¹³

International and national controls on the handling, storage, use and transfer of dangerous pathogens and toxins

12. The BTWC in Article III (Box 7.5) requires States Parties to provide such controls on pathogens and toxins.

Box 7.5: Article III of the BTWC.

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of this Convention.

At the Seventh Review Conference in 2011, States Parties reaffirmed that Article III is sufficiently comprehensive to cover any recipient whatsoever at the international,

national or sub-national levels, and called for all States Parties to adopt appropriate measures to implement this Article.

United Nations Security Council Resolution 1540 (2004)

13. UN SCR 1540 (2004)¹⁴ also addresses such controls, as it requires that “all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials”. The information provided to the 1540 Committee outlined in the previous section includes measures to establish appropriate controls.

14. Increasingly, there is national recognition that measures need to be taken to ensure that dangerous pathogens, toxins and other harmful materials are stored and used in ways that ensure that those who work with them, those who live in the vicinity of such facilities, and those at risk from their release, are not put at risk. This leads to national standards being required for the handling, storage and use of such materials, and for national controls of transfers between facilities.

15. There is recognition that disease knows no frontiers, and that hence it is vital to have international measures to ensure that dangerous pathogens, toxins and other harmful substances cause no harm, whether accidentally or deliberately. There are consequently international and regional standards for handling, storage and use of such materials, and for controls of transfers between States.

16. It is also accepted that measures to deal with dangerous pathogens and toxins must address any outbreaks of disease or instances of poisoning, whether occurring naturally, accidentally or deliberately. Consequently, the World Health Organization (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization (FAO) work together to address health risks at the animal-human-ecosystems interfaces.

Convention on Biological Diversity and the Cartagena Protocol on Biosafety

17. There is widespread cooperation between states that are members of the Convention on Biological Diversity¹⁵ and the associated Cartagena Protocol on Biosafety. Although these are primarily concerned with genetically modified organisms, their requirements do contribute to ensuring the safe handling and use of such organisms – and reduction of any risks to human health. The Cartagena Protocol requires that an advanced informed agreement procedure be followed, prior to the first intentional transboundary movement of modified organisms for intentional introduction into the environment.¹⁶

Green Customs Initiative

18. The Green Customs Initiative¹⁷ is a partnership of international organisations which cooperate to prevent the illegal trade in environmentally-sensitive commodities, and facilitate the legal trade in such commodities. Its objective is to enhance the capacity of customs and other relevant enforcement personnel to monitor and to facilitate the legal trade, and to detect and prevent illegal trade in environmentally-sensitive commodities covered by the relevant conventions and multilateral environmental agreements (MEAs). These include ozone depleting substances (ODS), toxic chemical products, hazardous wastes, endangered species and living-modified organisms. This is achieved through awareness-raising on all the relevant international agreements, as well as provision of assistance and tools to the enforcement community. The partners of the Green Customs Initiative comprise the secretariats of the relevant multilateral environmental agreements (Basel, Cartagena, CITES, Montreal, Rotterdam, Stockholm), INTERPOL, the Organisation for the Prohibition of Chemical Weapons (OPCW), UNEP, the UN Office on Drugs and Crime (UNODC), and the World Customs Organization. It is noteworthy that the Cartagena Protocol on Biosafety and the OPCW are both Green Customs partners.

Preparedness, including both active and passive protective measures and response plans that have been exercised

19. There is increasing recognition that States need to be prepared to respond to natural, accidental and deliberate outbreaks of human, animal or plant disease (see Figure 7.4).

Figure 7.4: Preparedness.



The World Health Organization (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization (FAO) have recognised the need to work together to address health risks at the animal-human-ecosystems interfaces. In a note issued in April 2010¹⁸ they recognised that: “The emergence of new or the re-emergence of existing animal diseases, including zoonoses, the growing threat of transboundary animal diseases, the impact of environmental changes and globalization, as well as new societal demands related to food security, food safety, public health and animal welfare, emphasize the critical need for collaboration

between the three organizations.” Furthermore, they encouraged “international solidarity in the control of human and animal diseases, while providing international support to member countries requesting assistance with human and animal disease control and eradication operations.”

20. The G20 Agriculture Ministers met in Paris in 2011 and in their Ministerial Declaration¹⁹ agreed that: “As far as public health, animal health and plant health are concerned, we stress the importance of strengthening international and regional networks, international standard setting taking into account national and regional differences, information, surveillance and traceability systems, good governance and official services, since they ensure an early detection and a rapid response to biological threats, facilitate trade flows and contribute to global food security. We encourage international organizations, especially FAO, the World Health Organization (WHO), the World Organization for Animal Health (OIE), the Codex Alimentarius Commission (Codex), the International Plant Protection Convention (IPPC) and World Trade Organization (WTO) to continue their efforts towards enhancing interagency cooperation.”

WHO Strategic Framework for Action 2012 – 2016 Laboratory Biorisk Management

21. The WHO in 2012 issued its Strategic Framework for Action 2012 – 2016 Laboratory Biorisk Management²⁰ which is aimed towards the development of sustainable global, regional and national plans relating to laboratory biorisk management. This recognises that: “Under the International Health Regulations (IHR (2005))²¹, all State Parties have made a legally binding commitment to assess, develop and maintain their national core capacities for surveillance, assessment and response.” It then goes on to observe that: “Although laboratory biosecurity is a relatively new concept to many, biosafety has been an established discipline for several decades. These fields have recently been elevated in prominence for a number of reasons, including laboratory acquired infections associated with SARS, the anthrax attacks in the US postal service, and renewed interest in the BTWC, together with emerging issues relating to the rapid growth of biotechnology and concerns over the potential for illicit use of such technologies.” It then adds that: “However, despite significant

investments in this field during the last decade, and progress made in strengthening biorisk²² management, many countries remain without effective regulatory and oversight mechanisms, and levels of awareness are often low amongst regulators and laboratory personnel alike.”

European Centre for Standardisation (CEN) Workshop Agreement (CWA)

Laboratory biorisk management

22. The reference in the WHO biorisk definition to CWA 15793:2011 is to a September 2011 report²³ on Laboratory biorisk management. This states that: “The scope of this laboratory biorisk management system agreement is to set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.” This CWA agreement is currently being developed into an international standard (ISO).²⁴

OIE Biological Threat Reduction Strategy – Strengthening Global Biological Security

23. In January 2012, the OIE issued their Biological Threat Reduction Strategy²⁵ in which they stated that: “The most effective and sustainable way to protect against threats from deliberate and accidental releases of animal pathogens is to strengthen existing systems for surveillance, early on-farm detection and rapid response, and for biosafety and biosecurity, whilst fostering scientific networks that work towards altruistic goals. This approach has multiple collateral benefits for animal health, agriculture, public health, poverty alleviation, animal welfare, and economies.” This strategy includes a section on International Cooperation.²⁶

FAO Biosecurity Toolkit

24. The FAO in 2007 issued its FAO Biosecurity Toolkit²⁷ which states: “Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment. Biosecurity covers food safety, zoonoses, the introduction of animal and

plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g. genetically modified organisms or GMOs), and the introduction and management of invasive alien species. Thus biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, and wide-ranging aspects of public health and protection of the environment, including biological diversity.” The toolkit sets out how the various stakeholders can work together in an integrated approach.

FAO Emergency Prevention System

25. Another FAO initiative is the FAO Emergency Prevention System (EMPRES) for Transboundary Animal and Plant Pests and Diseases,²⁸ established in June 1994 with the mandate to address prevention and early warning across the entire food chain. EMPRES also covers other transboundary diseases and pests that jeopardise food security, adversely affect public health, or impede international trade in livestock and animal products.

Other International Initiatives

26. In addition to the various initiatives that have been taken by the WHO, OIE and FAO, there have been various international initiatives taken either globally or within a region, such as by the European Union. The following sections first address four global activities:

- a. the Global Health Security Initiative (GHSI) which began in 2001;
- b. the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction established in 2002; and
- c. the Global Health Security Agenda (GHSa) launched in 2014;
- d. the United Nations Sustainable Development Goals agreed in 2015.

and the fifth goes on to address activities undertaken by the European Union.

Global Health Security Initiative (GHSI)

27. The GHSI²⁹ is an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of chemical, biological, radiological and nuclear terrorism (CBRN) and pandemic influenza. This initiative was launched in November 2001 by Canada, the European Union, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States, with the WHO serving as an expert adviser to the GHSI. The GHSI was envisaged as an informal group to fill a gap to address health issues of the day, such as global health security. The Initiative was not intended to replace, overlap or duplicate existing fora or networks.

28. In December 2014 the fifteenth Ministerial Meeting³⁰ took place in Tokyo, Japan, when key priorities for collective preparedness and response to CBRN threats, pandemic influenza and other emerging infectious diseases, specifically the Ebola Virus Disease (EVD) outbreak in West Africa, were discussed. In regard to strengthening longer-term preparedness, the fifteenth meeting agreed: “Since the creation of GHSI, Ministers and Senior Officials have reassessed the mandate, scope and membership of the network on various occasions based on lessons learned from events that impacted global health security and in response to members’ needs and priorities. An in-depth review in 2014 led to the establishment of a Strategic Framework that guides network engagement in policies, programs and activities in a common direction and that supports the GHSI mandate. Under the Framework, this work will take place in the context of key risks to global health security, specifically CBRN threats and the spread of pandemic influenza and other emerging infectious diseases across the following pillars: strengthen prevention; strengthen preparedness; rapidly detect threats and risks; respond effectively; and support recovery and build resilience. The Strategic Framework for GHSI recognizes that taking timely collaborative actions to address threats and risks will help mitigate the effects of potential future events and will also position the work of GHSI within the broader global health security landscape.” (Emphasis added)

Global Partnership Against the Spread of Weapons and Materials of Mass Destruction

29. The Global Partnership³¹ was established in 2002 at the G8 Summit and as of March 2013 it has 28 Members.³² The Global Partnership in 2011 agreed that biological security should be one of four priority areas; the other three priorities are nuclear security; scientist engagement in the WMD field; and implementation of UN SC Resolution 1540. In the following year, 2012, the Global Partnership member states agreed to focus their efforts on the achievement of “five biosecurity deliverables”³³:

- 1) Secure and account for materials that represent biological proliferation risks;
- 2) Develop and maintain appropriate and effective measures to prevent, prepare for, and respond to the deliberate misuse of biological agents;
- 3) Strengthen national and global networks to rapidly identify, confirm and respond to biological attacks;
- 4) Reinforce and strengthen biological non-proliferation principles, practices and instruments;
- 5) Reduce proliferation risks through the advancement and promotion of safe and responsible conduct in the biological sciences.

Global Health Security Agenda (GHSA)

30. The GHSA was launched³⁴ in February 2014 to advance a world safe and secure from infectious disease threats, and to bring together nations from all over the world to make new, concrete commitments, and to elevate global health security as a national leaders-level priority. The G7 (Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, the President of the European Council and the President of the European Commission) at their summit in Brussels in June 2014 endorsed the GHSA by declaring³⁵ that:

To address the threat posed by infectious diseases, we support the Global Health Security Agenda and commit to working with partner countries to

strengthen compliance with the World Health Organization's (WHO) International Health Regulations and enhance health security around the world. We commit to working across sectors to prevent, detect and respond to infectious diseases, whether naturally occurring, accidental, or the result of a deliberate act by a state or non-state actor. That includes building global capacity so that we are better prepared for threats such as the recent Ebola outbreak in West Africa and working together, in close cooperation with WHO, to develop a Global Action Plan on antimicrobial resistance. (Emphasis added)

The GHSA currently has forty-four participating countries, as set out in the 28 September 2014 Fact Sheet.³⁶

31. The GHSA has agreed eleven action packages³⁷ which have an underlying “Prevent – Detect – Respond” framework, effectively reflecting the concept of a web of prevention, as it recognises that these are complementary activities. One action package (GHSA Action Package Prevent-3) addresses Biosafety and Biosecurity with the leading countries involved being: Canada, Denmark, Kenya, Peru, Portugal and Spain, with contributing countries being: Azerbaijan, Germany, India (to be confirmed), Jordan, Republic of Korea, United Kingdom and United States. The contributing international organisations are: FAO, IAEA, INTERPOL, OIE and WHO. The Five-Year National Target for this Biosafety and Biosecurity Action Package is:

A whole-of-government national biosafety and biosecurity system is in place, ensuring that especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities according to best practices; biological risk management training and educational outreach are conducted to promote a shared culture of responsibility, reduce dual use risks, mitigate biological proliferation and deliberate use threats, and ensure safe transfer of biological agents; and country-specific biosafety and biosecurity legislation, laboratory licensing, and pathogen control measures are in place as appropriate.³⁸

United Nations Sustainable Development Goals

32. The United Nations General Assembly on 25 September 2015 adopted a resolution³⁹ entitled “Transforming our world: the 2030 Agenda for Sustainable Development”. This included as Goal 3. “Ensure healthy lives and promote well-being for all at all ages” with a sub-goal “3.d Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks” which is directly relevant to the activities of the WHO and the BTWC States Parties to enhance health security.

European Union

33. The above global initiatives all include the participation of the European Union (EU), which has taken significant steps and implemented an Action Plan⁴⁰ to enhance preparedness against CBRN events. The EU activities were updated⁴¹ in March 2014 in an EU Regulation, which in Article 5 states that the EU shall provide technical and financial assistance for the “mitigation of and preparedness against risks, whether of an intentional, accidental or natural origin, related to chemical, biological, radiological and nuclear materials or agents.” It is stated⁴² that such assistance shall include: enhancing safety practices related to civilian facilities where biological materials are stored or are handled, and also developing the legal framework and institutional capacities for the establishment and enforcement of effective export controls on dual-use goods, including regional cooperation measures.

EU CBRN Centres of Excellence (CoE)

34. In addition, the EU in May 2010 established a CBRN Centres of Excellence (CoE) initiative in order to strengthen the institutional capacity of countries outside the EU to mitigate CBRN risks, including criminal activities (e.g. CBRN proliferation or terrorism), natural disasters and accidental disasters. These activities are indeed global in their reach, and those relating to biological materials are directly relevant to the web of prevention.⁴³

Determined national and international response to any use or threat of use of biological weapons, ranging from diplomatic sanctions through to armed intervention

35. The fourth element of the web of prevention requires states to be determined not to allow any use or threat of use of biological agents or toxins to occur without an appropriate and timely response. A key component in this regard is the United Nations Secretary-General's mechanism to carry out prompt investigations in response to allegations brought to his attention concerning the possible use of chemical and bacteriological (biological) and toxin weapons, which was developed in the late 1980s.⁴⁴ Triggered by a request from any Member State, the Secretary-General is authorised to launch an investigation, including dispatching a fact-finding team to the site(s) of the alleged incident(s), and to report to all UN Member States. This is to ascertain in an objective and scientific manner facts of alleged violations of the 1925 Geneva Protocol, which bans the use of chemical and biological weapons, or of other relevant rules of customary international law.

36. In addition, the UN General Assembly continues to adopt resolutions to uphold the 1925 Geneva Protocol⁴⁵ and to prevent terrorists acquiring weapons of mass destruction – such as A/RES/69/39 adopted on 2 December 2014⁴⁶ which:

Recognizing the determination of the international community to combat terrorism, as evidenced in relevant General Assembly and Security Council resolutions,

Deeply concerned by the growing risk of linkages between terrorism and weapons of mass destruction, and in particular by the fact that terrorists may seek to acquire weapons of mass destruction,

Cognizant of the steps taken by States to implement Security Council resolution 1540 (2004) on the non-proliferation of weapons of mass destruction, adopted on 28 April 2004.

1. Calls upon all Member States to support international efforts to prevent terrorists from acquiring weapons of mass destruction and their means of delivery;

...

3. Urges all Member States to take and strengthen national measures, as appropriate, to prevent terrorists from acquiring weapons of mass destruction, their means of delivery and materials and technologies related to their manufacture;

4. Encourages cooperation among and between Member States and relevant regional and international organizations for strengthening national capacities in this regard;’

Conclusions

37. The web of prevention is thus an integrated and comprehensive approach in which all of the elements are complementary and reinforce each other, to create an effective counter to the threat of biological weapons, whether posed by states, non-state actors or other entities. This chapter has examined the various elements that contribute to the web of prevention, and identifies the contributions that are made from the wide range of existing international agreements and activities relating to the life sciences. The chapter clearly shows the vital contribution of biosecurity and biosafety to the web of prevention. It also makes clear that all those engaged in the life sciences, whether in government, industry or academia, must be aware of their responsibilities to protect their work from misuse, thereby contributing to the web of prevention.

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Chapter 8: Dual use and the progress of the life sciences: A case for promoting biosecurity and the responsible conduct of research

Gerald Walther

Key learning objectives

- i. Understand the emergence of the dual-use biosecurity debate;
- ii. Become aware of the initiatives directed at reducing the threat of misuse of life science research for malign purposes;
- iii. Develop an understanding of the gap between science and security perspectives about scientific research;
- iv. Recognise that there is a need for closer collaboration to develop scientifically sound security analyses of research and technology.

Introduction

1. This chapter examines the origins of the dual-use debate in the early 2000s, and how the discussion has increasingly involved a larger number and variety of actors. This expansion has in turn resulted in the development and adoption of initiatives and guidelines to reduce the likelihood that progress in the life sciences will be used for malign purposes. Yet these developments have not been met with enthusiasm by all parties involved – specifically, science communities have increasingly complained about this “interference” and “regulation” of their work. This chapter will thus end in a discussion of how the scientific community could address the security concerns about their work, without giving up their scientific freedom.

The origins of the dual-use biosecurity debate

2. The phrase “dual-use technology” originally encompassed technology that had both civilian and military use. It was a non-normative, value-free term and could potentially be viewed favourably by those advocating further military technology, as it created spin-offs for the civilian world as well.¹ As such, dual-use technologies were rather beneficial for the military, particularly after the Cold War, when it was less easy to convince politicians of the need for military research. A 1997 paper by Molas-Gallert identified several policies for dual-use technology transfer and discussed the benefits of each.² The meaning of “dual use” changed significantly after the terrorist attacks on the 11th of September 2001, and the subsequent anthrax letter attacks. “Dual use” suddenly became a normatively loaded word, which was first used in this manner in the report of the US National Research Council’s Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology (known as the Fink Committee), entitled Biotechnology Research in an Age of Terrorism, published in 2004.³ In the Report, dual-use technology in the life sciences became subject to a dual-use dilemma. The dilemma, according to the report, is that any advances in the life sciences could easily be misused for the development of biological weapons by malign actors.⁴ Selgelid further clarified the problem and argued that there are three potential definitions of dual-use science and technology:

- i. that which has both civilian and military application;
- ii. that which can be used for both beneficial/good and harmful/bad purposes;
- iii. that which has both beneficial/good and harmful/bad purposes – where the harmful/bad purposes involve weapons, and usually weapons of mass destruction in particular.

3. According to Selgelid, the debate about dual use invokes the third definition, because it implies grave harm and is used in the international community with this implicit meaning. Of course, these concerns are not entirely new: physicists working on nuclear power had to think about the use of their research for military purposes, which proved justified when the first nuclear weapons were used on Japan. And even among life scientists, there have been concerns in the past about the impacts of their

research. The Asilomar Conference on Recombinant DNA (Box 8.1), held from the 24th to 26th of February 1975, was initiated because “scientists were concerned that unfettered pursuit of this research [DNA research] might engender unforeseen and damaging consequences for human health and the earth’s ecosystems.”⁵

Box 8.1: Asilomar Conference in 1975.



The Asilomar Conference involved the majority of all scientists working with recombinant DNA techniques. Yet, the total number of attendees was only 140. Pictured left (left to right): Maxine Singer, Norton Zinder, Sydney Brenner, and Paul Berg. Source: National Academies of Science Archives. Used with permission.

4. Already during the conference, when DNA research was in its infancy, issues of dual use had been discussed. For example, “there were speculations that normally innocuous microbes could be changed into human pathogens by introducing genes that rendered them resistant to then-available antibiotics, or enabled them to produce dangerous toxins, or transformed them into cancer-causing agents.”⁶ Eventually, a set of guidelines, the National Institutes of Health’s Guidelines for Research Involving rDNA Molecules, was introduced, which are still in effect in modified form.⁷ In its section on previous challenges, the Fink Report mentions both the developments at Asilomar as well as the discussions that had taken place as part of the Human Genome Project. The problem for the Fink Committee was that these discussions of dual use had been forgotten. One reason for this is that the National Institutes of Health Guidelines, which originally addressed dual-use dilemmas, were changed several times because, despite an increase in the number of researchers using rDNA techniques, no misuse of the technology had been reported, and because of a hope that

less strict policies would speed up the process of understanding diseases. Eventually, the only guidelines that were left dealt with research on molecular manipulation of human and restricted plant and animal pathogens.⁸ The Fink Committee therefore had to revisit the life sciences completely anew.

The Fink Committee: origins and events

5. In addition to the historic developments with regard to dual use, there were specific contemporary events that directly influenced the work of the Committee. This section will outline some of the developments that directly led to the inception of the Committee, in order to show why the problem of dual use attracted so much attention in 2001.

6. In 1975, the Biological and Toxin Weapons Convention (BTWC) entered into force, and prohibited states from the development, production, and stockpiling of any form of biological weapon. Although the Soviet Union signed and ratified the Convention, it continued to pursue offensive biological weapons research and produced a variety of highly dangerous biological agents (for a more detailed description of the work carried out see Chapter 3).⁹ Against the background of the subsequent revelations about the Soviet programme, US security analysts became increasingly concerned that 'Rogue States' might pursue biological weapons research as well. In 1993, the Office for Technology Assessment produced a study that compared the destructive ability of nuclear, chemical, and biological weapons and found that, while chemical weapons are not as dangerous as a nuclear bomb, biological weapons are capable of killing and injuring as many people as a nuclear weapon does.¹⁰ In May 2000, Matthew Meselson, a renowned molecular biologist, warned against the potential misuse of biotechnology¹¹ (see Chapter 3). In June 2001, an exercise called 'Dark Winter' was held, which simulated a smallpox attack infecting a total of 3000 people in three US cities. The analysis of the reactions of high-level US politicians and civil servants led to the conclusions that policy makers were ill-equipped to deal with this sort of terrorist attack.¹² Of course, a few months later the concerns about the use of a biological weapon by terrorists proved valid in the aftermath of 9/11, with the sending of the anthrax letters through the US postal

service, which not only resulted in several deaths, but also cost 320 million US\$ to clean up.¹³ Also, several reports had begun to appear in the scientific literature of the use of modern biotechnology methods for the creation of dangerous microorganisms of dual-use character.¹⁴

7. In addition, there had been important developments with regard to the BTWC, particularly during the period before the Fifth Review Conference in 2001 (see Chapter 6). One of the main impediments to a strong BTWC had always been the lack of a regime to monitor if countries actually comply with the Convention. In the period leading up to the 2001 Review Conference, a strong push for a verification instrument had been made, culminating in the negotiations on the ‘composite text’ proposed by the Chair Tibor Tóth; this was the result of the meetings of the “Ad Hoc Group,” which had been tasked with creating a Verification Protocol. However, the US rejected the text and refused to continue the negotiations, because it did not perceive a verification instrument to be effective in ensuring the goals of the BTWC¹⁵ (see Chapter 6). At the 2001 Review Conference, the US agreed to hold annual meetings and allow the establishment of expert groups, if the Ad Hoc Group got terminated in return. In order to be able to deal with the chaos resulting after this proposal, the Chair adjourned the Conference until November 2002. One of the outcomes of the resumed Conference was the agreement on an Intersessional Process in order to keep the dialogue going on how to strengthen the BTWC in the future.

8. Two observations can be made, based on this history. First, the Amerithrax attack highlighted the danger that scientific work could be misused for malign purposes, which contributed strongly to the creation of the Fink Committee. Second, the problem received further attention, because of the events at the 2001 Review Conference and a subsequent lack of direction for the BTWC. The problem of dual use posed an uncontested topic for the Convention, as it steered clear of any talks about a verification regime. The next section will show how the Fink Committee aimed to address the dual-use problem.

The effects of the Fink Committee

9. The Committee based its recommendations on the conclusion that it drew from an analysis of the then current state of regulation of science and technology. It concluded that “existing domestic and international guidelines and regulations for the conduct of basic or applied genetic engineering research may ensure the physical safety of laboratory workers and the surrounding environment from contact with, or exposure to, pathogenic agents or “novel” organisms. However, they do not currently address the potential for misuse of the tools, technology, or knowledge base of this research enterprise for offensive military or terrorist purposes. In addition, no national or international review body currently has the legal authority or self-governance responsibility to evaluate a proposed research activity prior to its conduct to determine whether the risks associated with the proposed research, and its potential for misuse, outweigh its potential benefits.”¹⁶

10. The Committee’s way to address this problem was to engage life scientists in a dialogue to raise awareness of the dual-use issue, and to develop a system for communication as well as oversight. The central idea was that this system would involve a number of stages, at several levels of research, to review research and consider its potential dual-use implications. The system would rely mainly on self-governance by the scientific community. In order to assist the scientists, a set of guidelines was to be set up to help identify potential experiments of concern.

11. One notable recommendation was to establish a permanent body to discuss the issues that the Fink Committee had been working on. Besides the creation of this new body, the recommendations mainly targeted the scientific community, who were charged with expanding their education to include the ethics of dual use, modifying their current way of publishing, and creating communication channels with the security and law enforcement communities. The recommendations of the Fink Committee are reflected in what is described as the “web of prevention,” which according to a 2003 International Committee of the Red Cross publication “should serve to prevent advances in biotechnology being used for poisoning or the deliberate

spread of disease.”¹⁷ The web is supposed to draw in several different types of actors, as discussed in Chapter 7 of this Guide.

Actors beyond Fink

12. The Fink Committee was not the only forum or organisation where the topic was debated in these early stages. In 2003 a UN InterAgency Consultative Meeting discussed dual use and codes of conduct for scientists, while the British Society for General Microbiology issued a Policy on Scientific Publication, Security and Censorship¹⁸, which was updated in 2014 with its position statement on Biosecurity and the Dual-Use of Research.¹⁹ In the UK, the House of Commons Science and Technology Committee debated the issue of a code of conduct, and eventually the UK Government initiated a series of workshops involving scientific, medical and industrial communities on this topic.²⁰ At the end of 2003, the UNESCO’s World Commission on the Ethics of Scientific Knowledge and Technology discussed the introduction of a code of conduct for scientists, with particular reference to biological weapons.²¹ In Asia, members of the Asia-Pacific Economic Cooperation discussed the introduction of a similar code of conduct for scientists.²² Also, a joint statement by the editors of several high-profile scientific journals about their commitment to biosecurity, was published in a Nature editorial in 2003.²³ This statement endorsed the idea of making biosecurity an issue that needs to be addressed in the review of scientific articles, as well as in the general communication of scientific information. In 2004, the number of actors working on codes of conduct and biosecurity increased even further. Actors included the UK’s Royal Society and the Wellcome Trust²⁴, the American Medical Association²⁵, the InterAcademy Panel²⁶, the Organisation for Economic Co-operation and Development’s International Futures Programme²⁷, the British Medical Association²⁸, and the International Committee of the Red Cross.²⁹ Also, the UN adopted Resolution 1540, which requires all States to develop oversight arrangements “to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing controls over related materials”³⁰ (see Chapter 7).

13. In July 2005, the International Union of Microbiological Societies held a meeting where they discussed a Code of Ethics Against Misuse of Scientific Knowledge, Research and Resources, which was finally adopted by the General Assembly in October 2006.³¹ This code of ethics was primarily based on work of the American Society for Microbiology on this topic. Also in 2005, Somerville and Atlas proposed a ‘Code of ethics for the life sciences’, which was published in Science and therefore presumably reached a wide audience of scientists.³²

14. After this initial burst of activities in the form of workshops, committees, and reports, the issue received less attention in the following years: however, this does not imply that no work was done. For example, at the 6th Review Conference of the BTWC in 2006, India, Japan, Pakistan, and the UK all made statements in support of codes of conduct. The States Parties agreed on a new set of intersessional meetings, which included the topic in 2008 of “Oversight, education, awareness-raising, and adoption and/or development of codes of conduct with the aim to prevent misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention”.³³ During the 7th Review Conference in 2011, the State Parties agreed to “include in the 2012-15 intersessional programme a standing agenda item on review of developments in the field of science and technology related to the Convention.”³⁴

15. The debate about science and technology primarily focussed on the field of synthetic biology, because this research was deemed to raise considerable dual-use issues. However, recently neuroscience has started to receive attention as well: for example, a publication by UK’s The Royal Society focused specifically on the security and conflict implications of neuroscience research.³⁵ In the US, the National Research Council also identified neuroscience as a very important topic for future research for the military.³⁶ These developments in terms of broadening the scope of the discussions on dual use are also due to a second committee that took up the work of the Fink Committee: the Committee on Advances in Technology and the Prevention of their Application to Next Generation Bioterrorism and Biological Warfare Threats – or in short, the Lemon-Relman committee. The Committee published their report Globalization, Biosecurity and the Future of the Life Sciences in 2006 (Box 8.2).³⁷ While the report reasserts the concerns of the Fink Report, it

differs markedly in widening the scope of the scientific fields which could give rise to dual-use concerns. The main reason for this difference between the two reports was that the Fink Committee had been charged to focus only on synthetic biology, while the Lemon-Relman Committee was not limited to a specific field. This change in focus to consider all life sciences resulted in the conclusion that all life science research could be prone to misuse. Thus, unlike the Fink Report, the Lemon-Relman Report did not produce a list of experiments of concern. While this change in perspective might appear innocuous at first glance, it had far reaching consequences, as the next section will highlight.

Box 8.2: The Lemon-Relman Report increased the scope of the dual-use problem by arguing that all life science research is prone to misuse



Biosecurity appears on the radar of life scientists

16. By arguing that all life science research should be analysed with regard to its dual-use potential, the Lemon-Relman Report opened the door for discussing the security

threats of all such scientific work. However, apart from sporadic discussions surrounding a few experiments, nothing major happened until 2011. Until then, the majority of the scientific community had never been exposed to the idea that their research could present a security risk. One reason is that university courses in general life sciences^{38, 39, 40} or specialised courses, e.g. neuroscience,⁴¹ generally do not discuss dual-use biosecurity issues. This lack of exposure is particularly noteworthy, given the range of activities discussed in the previous section which, despite the wide range of actors involved, never reached the scientific community at large. In 2011 part of the scientific community, particularly microbiology and virology, was therefore caught off-guard when the heated debate surrounding the controversial H5N1 influenza virus experiments⁴² ensued (see Chapter 2 of this Guide for a discussion of these experiments and a chronology of events; also Box 8.3). This debate showed a lack of engagement on the part of the scientific community in dealing with the problem of dual use.

Box 8.3: A glass sculpture of H5N1 by the artist Luke Jerram. His glass constructions of biological material intend to bring biology closer to the public by making them tangible.

Source:

<http://www.lukejerram.com/glass/>

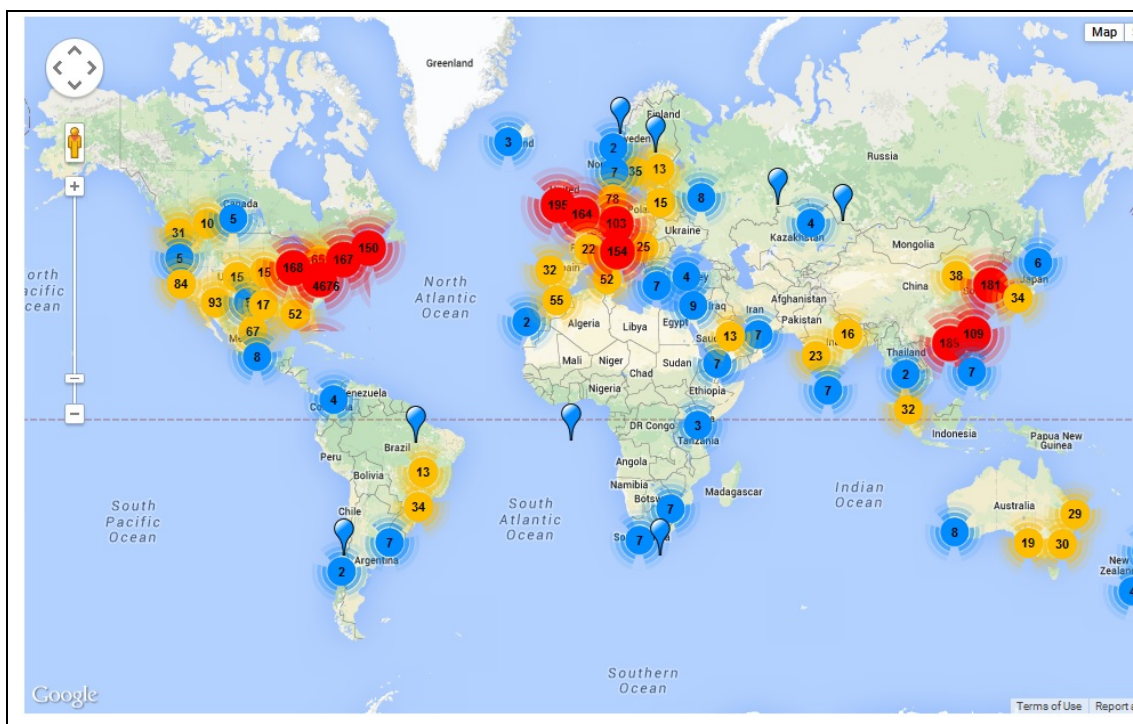


17. One of the key protagonists in the H5N1 debate was the US National Science Advisory Board for Biosecurity. It was chartered in March 2004, following the

recommendation of the Fink Committee: it consists of 25 voting members from a variety of disciplines: natural sciences, public health, biosecurity, intelligence, scientific publishing and laboratory safety. The group is tasked with advising the Government on dual-use issues in the life sciences. Until the H5N1 influenza case, the National Science Advisory Board for Biosecurity had reviewed several experiments and, while they had some concerns about them, they did not have any reservations about their publication.

18. What can be concluded from the debate surrounding the H5N1 case, is that it has been difficult for the scientific community to understand biosecurity concerns and, conversely, for the biosecurity community to understand this lack of concern and opposition to discussions about the security implications of scientific research. For the most part, discussions about the security risks of scientific experiments have only involved actors in the security arena. Kathleen Vogel argues in a 2008 article that this one-sided engagement with the topic is counter-productive to both science and security.⁴³ According to her, these discussions on biotechnology and its associated risks have taken place within a specific biosecurity framework. Vogel argues that, according to this frame of debate, the future of biotechnology is depicted as one in which it will become increasingly easier for others, i.e. non- or lay-scientists, to use modern scientific tools and methods (see Box 8.4). This increase in use is then used to create the impression that the development of a biological weapon by terrorists is inevitable. Adherence to this point of view has important ramifications for science and security policy. For example, policy initiatives focus on the threat and risk from future biotechnologies. Yet this worldview is not the only one available, and is potentially counter-productive for public security. Vogel analyses two specific examples, where experts predict a security problem in the future, to show how difficult it is on the ground to work with novel biotechnologies.

Box 8.4: Next Generation Genomics: World Map of High-throughput Sequencing.



This map shows the number of high-throughput sequencing devices worldwide. Some security experts and scientists are worried that the dispersion of modern biotechnology will enable easier development of a biological weapon. The map is constantly updated at <http://omicsmaps.com/>. This map is from the 26th of March, 2015.

19. Vogel's first example concerns the research on artificial polio synthesis conducted by the virologist Eckard Wimmer and his group, which was published in Science in 2002.⁴⁴ The second example is the work done by researchers from the J Craig Venter Institute, published in 2003, who used an alternative method for artificially synthesising the ϕ X174 bacteriophage.⁴⁵ While it took Wimmer's group three years to complete the synthesis, the Venter work was simpler and faster: they managed to accomplish their synthesis in only two weeks. Vogel reports that these two experiments have been cited over and over again at security conferences and in articles about the dangers of scientific research. The concern was always that, if these groups could manage their work this quickly, it would be easy for non-scientists to perform similar experiments in the future, as science gets better and more accessible.

What Vogel did was to talk to both of these groups to better understand the scientific expertise needed to conduct the experiments. What she found was that elements such as “particular intellectual insight, laboratory practices, team-work, and troubleshooting efforts” play crucial roles in achieving the results.⁴⁶ Thus, while the security concerns related to these two experiments may appear reasonable to non-scientific laymen on the outside, anyone working on these experiments knew just how difficult this work was, and that it could not be easily reproduced by anyone who was not part of their group. These insights into actual use of biotechnology run counter to the dominant security framework that subscribes to the inevitability of the biotechnology revolution argument – namely to a narrative which accepts that biotechnology will be deployed for hostile purposes. As a result, Vogel argues that a different framework is more suitable to address the issue of biosecurity. In her alternative frame, attention is paid to the socio-technical aspects of technology, e.g. the tacit knowledge required for being able to use technology. Her framework is also not exclusively directed to the future, but also pays attention to the use of current technologies and their risks. Vogel’s analysis supports what Lemon-Relman had already discussed in 2006, which is the lack of scientific expertise within the security community. However, it may be somewhat unfair to criticise the security community. After all, it may actually not be their fault that the scientific expertise is missing in security analyses. The scientific community needs to actively engage with the question of dual use in a way that goes beyond the defensive position which is currently common, in which scientists simply proclaim the sanctity of the freedom to research and publish, without any constraints or considerations for the societal impact of their work. One way forward is to actually go back to the very first recommendation by the Fink Committee, which was to educate scientists about dual-use biosecurity. Even though this recommendation was made more than 10 years ago, not much progress has been made in this regard.^{47, 48} Yet, this development is crucial, if the field is to move beyond the current adversarial positions between science and security.

20. One recent example may be helpful in illustrating how scientific research can be conducted with awareness of the security responsibilities. In October 2013, a new type of Botulinum Toxin – type H – was discovered. The researchers also identified and characterised the gene that produced this new type H. Furthermore, they discovered that the available antitoxins against the other botulinum types (A-G) do

not work on the new type. As a result, the researchers contacted the editors of the Journal of Infectious Diseases to argue that full publication of the gene sequence could be problematic, as it could be misused as a biological weapon. The editors agreed and allowed partial publication, which was sufficient to show that the partial gene sequence is indeed novel, but does not contain enough information to enable artificial synthesis. Once an antitoxin is found to the new type, the full sequence will be released. This case provides a good example of where researchers were aware of the wider implications of their research and acted responsibly. Unfortunately, this case presents only half of the dual-use story. It was relatively simple for the scientists to withhold the information, because there was a scientific solution to the problem – the antitoxin. In other cases, such as H5N1, there is no such silver bullet. Nevertheless, without any security awareness among the scientific community, examples of the responsible behaviour displayed in this case might not occur at all, which would create even more security concerns.

Conclusions

21. While the term “dual use” has been around since the earliest interaction between science and the military, dual-use biosecurity emerged as a novel concept after the anthrax letter attacks in the US in 2001. It asks the question of how to ensure that life science research will not be misused for malign purposes, i.e. bioterrorism. While early commentators, e.g. the Fink Committee, already identified dual-use biosecurity education for scientists as one of the key components to ensure this goal, lack of progress in this area has resulted in a position where science and security have increasingly been viewed as being in conflict. In addition, while progress has been made in some areas, e.g. biosecurity is supposed to be a criterion against which reviewers are to judge scientific publications, these measures can only be effective if the scientific community is aware of the problem in the first place. Similarly, the security community has suffered from a lack of scientific input, which has resulted in concerns being raised about scientific research that may be justifiable if only viewed from a security perspective, but become non-issues when scientists are actually asked about the technical expertise that is essential for carrying out the research. What is required is an ongoing cooperative dialogue in which security experts and scientists

discuss the potential dangers from scientific research and how these could be reduced, both by carrying out responsible research on the part of the scientists, and implementing reasonable policies on the part of the security community (see Chapter 12).

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Chapter 9: The role of industry in promoting biosecurity: a case study of convergence of chemistry and biology

Ralf Trapp

Key learning objectives

- i. Understand the concept of convergence, and develop an appreciation for how different scientific and engineering disciplines combine to create new understandings in the life sciences;
- ii. Understand the basic design of the global regimes that ban chemical and biological weapons, and appreciate how these regimes may be affected by convergence;
- iii. Appreciate that sustaining these global norms and making them resilient will require top-down (regulatory) as well as bottom-up (voluntary) measures;
- iv. Understand why industry is not merely the object of regulations and controls, but needs to be a partner of governments in ensuring safety, security and treaty compliance.

Introduction

1. Ensuring biosecurity requires, in addition to proper regulation, awareness and active contribution by all stakeholders, including industry. How industry can contribute effectively to strengthening security can be seen from the role that the chemical industry has played in adopting and implementing the Chemical Weapons Convention. This chapter, initially, provides an overview of the international norms that prohibit chemical and biological weapons. It then looks at the intersection between chemistry and biology, and explains how science, technology and industrial application are converging there, and what that means for these international regimes. Finally, it discusses what role industry can and should play to promote biosecurity, and to manage the risks associated with its products, facilities and activities.

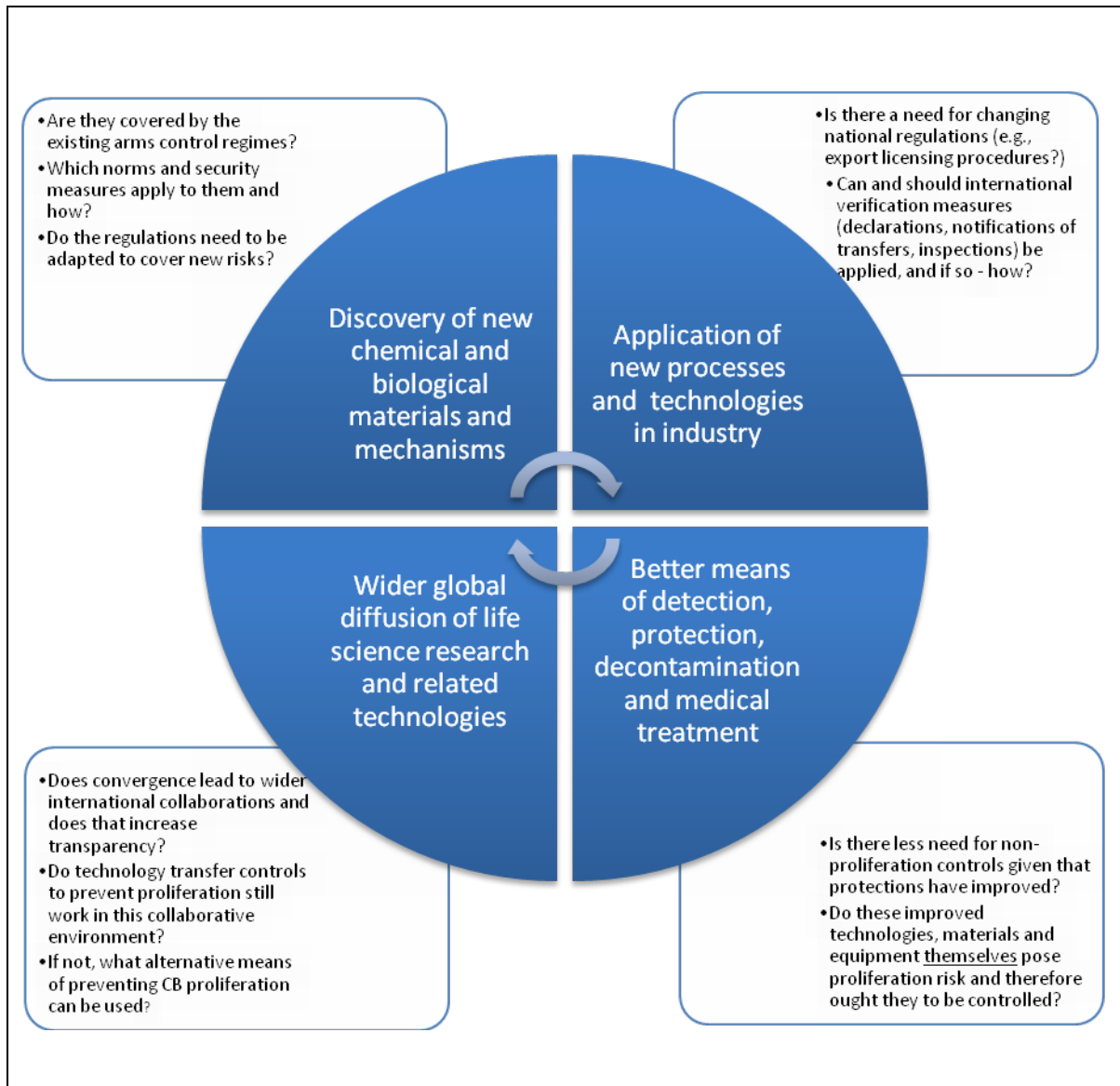
Convergence of chemistry and biology, biosecurity and arms control

2. Advances in science and technology have traditionally followed two distinct directions. Either, scientists have narrowed down their fields of inquiry and created multiple scientific sub-disciplines, thus reducing complexity and making it possible to study in great detail specific phenomena of the natural world; or they have tried to integrate knowledge and experimental methods from different disciplines to broaden their understanding of the functioning of complex systems, such as biological organisms.

3. At the turn of the 21st century, such integrative approaches have become a characteristic feature of the life sciences. This convergence has been described as “integrative and collaborative trends in the life sciences that bring together theoretical concepts, experimental techniques and knowledge of different science and engineering disciplines at the intersection of chemistry and biology. Such interdisciplinary approaches often revolutionise scientific discovery and open up new areas of application of science and technology in society”¹ (emphasis added). Increasingly, convergence is also manifest in industry, with biomediated manufacturing of chemical products, and chemical synthesis of products, which have hitherto been made only by using biological methods.

4. Scientific progress, and the convergence which accelerates it, can affect security in several ways (Box 9.1). To understand how convergence relates to security and arms control, we shall first look at how the current international system has evolved, and how it relates to the world of science and technology.

Box 9.1: How convergence may affect existing arms control and security regimes.



The existing regimes prohibiting chemical and biological weapons

5. Throughout history, chemical weapons (poison used as a weapon) and biological weapons (disease used as a means of warfare) were considered together in international law.² As disease theory evolved during the nineteenth and twentieth century, many practical aspects related to their use and to protection against them began to separate. Nevertheless, humanitarian and arms control law continued to treat them as one category. This changed in 1972 when the BTWC was concluded, whilst negotiations of the Chemical Weapons Convention were to continue for another two decades.

6. The reasons for this division were pragmatic. It had become clear that agreeing a global ban on chemical weapons would take time because:

- i. The existence of significant chemical weapons stockpiles meant that provisions had to be negotiated for their verified destruction, and for the elimination of their production facilities;
- ii. Agreements had to be reached on the scope and comprehensiveness of the prohibition;
- iii. The existence of a chemical industry meant that international verification through on-site inspection was essential, to prevent the future reacquisition of chemical weapons.

On the other hand, a global ban on biological weapons was achievable: there were no publicly acknowledged stockpiles of biological weapons to be verified and destroyed; biological weapons had not been integrated into military doctrines; their military value remained doubtful; and consequently the absence of verification was not seen as a serious impediment to disarmament.

7. The separation of the biological and chemical regime also reflected differences in science and technology. The chemical industry was a mature industry that had evolved for more than half a century, and was a basis for national economies and an important driver of development. Any ban on chemical weapons needed to provide assurances that industrial chemical plants and trade were not being used as a cover for clandestine chemical weapons production.

8. On the other hand, a biological industry that reached beyond the traditional growth processes and products (food, beverages, vaccines and antibiotics) had yet to emerge. The risks associated with these well-established technologies were considered moderate, given the perceived limited military value of traditional biological weapons. Recombinant DNA work was only just beginning, and the use of genetically modified organisms in industrial production had yet to be realised in practice.

9. As a consequence, two distinct legal regimes have evolved (Box 9.2). The Chemical Weapons Convention is based on a combination of national implementation

and international verification measures, with an international organisation (the Organisation for the Prohibition of Chemical Weapons) that oversees its implementation. The BTWC is based on the actions of the States Parties themselves, supported by a small Implementation Support Unit (see Chapter 6 and Chapter 11). Both Conventions rely on what is known as a General Purpose Criterion – they comprehensively cover all known as well as unknown agents that have no justification for permitted purposes.

Box 9.2: The Chemical Weapons Convention and the Biological and Toxin Weapons Convention – a comparison of key aspects.

Chemical Weapons Convention	Biological and Toxin Weapons Convention
Organisation for the Prohibition of Chemical Weapons, with a Technical Secretariat led by the Director-General	Annual meetings of the States Parties, supported by a small Implementation Support Unit
International verification based on declarations and on-site inspections of government and industry facilities	National implementation measures by Member States, confidence building measures, and international consultative procedures to resolve concerns about compliance
Standing organs that meet regularly and decide on implementation matters (Conference of the States Parties, Executive Council)	“Intersessional process” with two meetings per year (Meeting of Experts and Meeting of the States Parties)
Scientific Advisory Board provides advice to the Director-General and Member States	Advances in science and technology constitute a standing agenda item in the intersessional meetings

5-yearly Review Conferences provide strategic orientation and decide on actions	5-yearly Review Conferences to review progress made - the only decision making forum
General Purpose Criterion: Any chemical or biological agent is prohibited, unless it is intended for legitimate purposes; it is legitimate only as long as its types and quantities are consistent with such legitimate purposes	

Convergence: a revolution in the life sciences

10. Convergence can be rationalised as two complementary concepts: chemistry is being used to ‘make biology’, and biology is being applied to ‘do chemistry’.³ In 2014, the Scientific Advisory Board of the Organisation for the Prohibition of Chemical Weapons (see also Box 9.3) assessed how this affects the Chemical Weapons Convention. It concluded as follows:⁴

- i. Bulk and fine chemicals are increasingly being produced using biologically mediated processes, e.g. by microbial fermentation or using enzymes as catalysts. It is estimated that approximately 10% of chemical production volume will use such processes by 2020. This trend is being driven by commercial and environmental factors, and particularly by competition for conventional feedstock;⁵
- ii. Key enabling technologies have resulted in a rapidly expanding capability to redesign or manipulate organisms for specific purposes, and the ability to design and engineer improved enzymes (such as through metabolic engineering, enzyme engineering, synthetic biology, or traditional recombinant DNA technology);
- iii. In parallel to biotechnological innovation, substantial advances have been made in the chemical synthesis of molecules of biological origin. Commercial DNA synthesis has advanced to the point where whole genomes can be synthesised and compiled, and viruses, including influenza and corona virus, have been reconstructed. Parallel research has enabled the rational engineering of viral capsids;

iv. Advances in the semi-automated synthesis of peptides have enhanced the ability to synthesise bioregulatory chemicals that mediate functioning of the body and other peptides with high physiological activity. Increased sophistication in organic chemistry has enabled the chemical synthesis of increasingly more complex biological molecules, including toxins, although generally on a scale that poses no threat to the purposes of the Convention;

v. Enabling technologies have been, and will remain, critical factors affecting the pace of change and convergence in the life sciences. Key technologies contributing to, and benefitting from, the convergence of chemistry and biology include: DNA sequencing and synthesis, informatics, computing capacity, availability and sharing of technical data on the Internet, and automated robotics in research and development. Multidisciplinary research teams are becoming the norm, encompassing a range of technical expertise, including chemistry, biology, physics, computing, engineering, materials science and nanotechnology.

Box 9.3: The Scientific Advisory Board of the Organisation for the Prohibition of Chemical Weapons.



Some issues on the SAB agenda in 2015:

- i. Developments in science and technology, including convergence
- ii. Scientific and technological elements of verification methodologies
- iii. Emerging technologies and new equipment
- iv. Scheduled chemicals (chemicals listed in the Convention's control lists for verification purposes)

Synthetic and systems biology

11. An area of convergence that has received much attention is synthetic biology. The International Union of Pure and Applied Chemistry described it as “controlled construction of biological systems”.⁶ Others emphasise its potential to synthesise

biological structures or life forms in the laboratory, as well as molecular structures and/or multi-molecular organised biological systems that do not exist in nature.⁷

12. Techniques that are shaping this type of work include faster, more accurate and cheaper DNA synthesis, whole genome cloning, the automated design of biological pathways, synthetic chromosomes, editing of the genetic code, RNA structural engineering, customised genetic circuits, and applications based on synthesised cells and predictive genome engineering.⁸ The tools used in synthetic biology are continuously evolving. Experiments that a short while ago required considerable time, skill and resources are now being routinely carried out in laboratories around the world. An example is the use in genome editing of Clustered Regularly Interspaced Short Palindrome Repeats (CRISPR)/CRISPR-associated (Cas) endonuclease (CRISPR/Cas) systems; those use guide RNA to target the endonuclease to specific DNA sequences.⁹ This tool has proven transformational as it is simple, easy to use, and cheap.

13. Synthetic and systems biology are the result of a symbiosis between biology, engineering and information sciences (including mathematical modelling and computing). Standardised biobricks¹⁰ with well-characterised and reproducible functionality, and biological circuits to create biological switches and memory elements¹¹ are examples of synthetic biology; simulation models for biological circuits are examples of systems biology.

14. Synthetic and systems biology represent a fundamental refocus in biology from individual proteins to complex systems and interacting molecular networks.¹² Biology is gradually evolving from a predominantly descriptive to a deductive discipline, that attempts to predict the behaviour of biological systems from first principles: “genomics, transcriptomics, proteomics and metabolomics together provide a set of tools in synthetic biology that can be used to design organisms with desired properties”¹³ (emphasis added). This holistic approach results in a growing understanding of the relationship between the genome and cell behaviour. The genetic base code of all cells of an organism is of course the same, but genes are expressed differently depending on a cell’s function, environment, and immediate context. It is not the genome itself that determines the behaviour of a cell, but the interaction of a

discrete number of smaller molecules (mRNA, proteins, metabolites) present in the cell with the genome and with each other. These “lower-level” systems (transcriptome, proteome, and metabolome) are increasingly better understood, as the generation of ever-increasing libraries of reliable biological data complements the application of mathematical algorithms to analyse these large data sets and model the behaviour of dynamic systems. Huge challenges remain, and the complexity of biological systems (their “fuzziness”) continues to pose fundamental obstacles to rational design. Nevertheless, efforts to create a living organism *ab initio* are well under way. The tools of synthetic and systems biology have been used to insert a synthetic ‘minimal genome’ cloned in yeast into a recipient bacterial *Mycoplasma capricolum* cell,¹⁴ to re-create pathogenic viruses,¹⁵ and to model an entire cell.¹⁶

Biological and biologically mediated processes

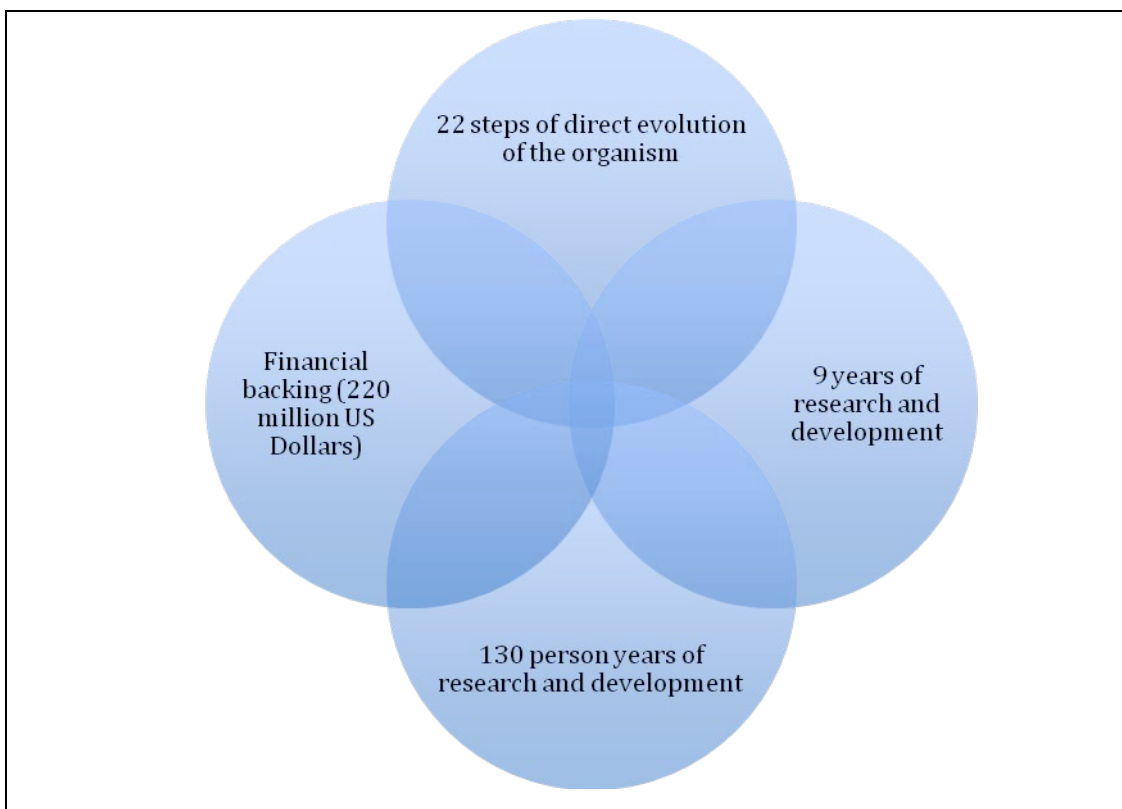
15. One result of these developments is the growing industrial application of biological processes, driven by, amongst other factors, the search for alternative raw materials, the need for renewable resources, the scarcity of certain natural products that are used in medicine and other applications, and the striving for ‘green technologies’. A range of biological processes is in industrial use today, from traditional fermentation to metabolically engineered organisms, enzymes (biocatalysts), and methods derived from synthetic biology.¹⁷ Examples include the production of:¹⁸

- i. Biofuels and biolubricants;
- ii. Lysine (a food additive) using *Corynebacterium glutamicum*;
- iii. Xanthan (a thickener used in food and personal care products) using *Xanthomonas campestris* pv. *Campestris*;
- iv. Acarbose (a medication used in diabetes type II treatment) using *Actinoplanes* sp.;
- v. Anthranilic acids such as anti-allergic tranilast, using modified yeast strains;
- vi. Artemisinin (an anti-malaria drug), using a genetically modified yeast, combined with chemical processing.

16. The Scientific Advisory Board of the Organisation for the Prohibition of Chemical Weapons pointed to a survey published in 2012, that identified 68 products across seven sectors (including biofuels, chemicals, energy, food, materials, and medicine) that are being developed by companies in 10 countries.

17. A well-published example is the manufacturing of artemisinin, using a combined chemical and biological process.¹⁹ The only natural source of this malaria drug is the sweet wormwood (*Artemisia annua*), which meant that availability and cost of the drug varied considerably, depending on the yield of the annual crop. The Gates Foundation supported the development of an industrial production method for the drug, using genetically modified yeast. To engineer this organism to be efficient and resistant in an industrial production environment was quite a challenge (Box 9.4).

Box 9.4: Engineering an organism suitable for industrial production – the example of Artemisinin.



18. Developing a production process to industrial scale does not merely involve the engineering of an organism that performs the desired function. The organism also must survive and maintain its efficiency in industrial production equipment, despite

variations in the compositions of the starting materials, fluctuations in process conditions, and environmental factors that might inhibit the process. Extensive testing is necessary, and the development of a viable and scalable production process takes time and resources.

19. Today, an industrial artemisinin plant using this process operates in Brazil. The experience gained, the tools developed (for example gene sequences with specific and well-characterised effects), and the knowledge about the pathway, are being used to automate many of the repetitive processes in research and development, and to develop industrial processes for molecules that can be constructed using the same pathway, but now with considerably less investment and time. An example is the production of farnesene (a synthetic building block used in manufacturing a range of product groups).²⁰

Enabling technologies

20. Enabling technologies such as the Internet (as a communications platform, knowledge depository and place for collaborations and commerce), large-volume computing and automation are important drivers that facilitate the diffusion of research capacity, and help transfer innovation to applications in society. Specifically, technology as an enabler can:

- i. Make possible the conduct of experiments that were not possible in the past – for example the use of additive manufacturing (3D printing) to create biological structures such as tissues, or complicated process equipment;
- ii. Facilitate the conduct of experiments by a large number of researchers, when previously only a few, well-trained and experienced researchers had the required skill set and equipment (“de-skilling” as well as reduction in costs) – an example is the use of CRISPR/Cas9 in genome editing;
- iii. Provide tools to apply results of life science research to practical applications - examples are the use of nanotechnology for the targeted delivery of drugs and/or to release drugs under predetermined physiological conditions to increase therapeutic efficiency and reduce side effects, or of antibody-drug conjugates for the specific delivery of cytotoxic payloads to target cells;

iv. Compress the time from scientific discovery to wider utilisation in research and society – an example being computational methods, software tools and programming languages used in designing and producing recombinant vectors.

21. But enabling technologies also shape the environment in which life science research is being conducted. The National Academies pointed to the following trends:²¹

- i. Easier collaboration between individual investigators, global networks of researchers, and the emergence of ‘virtual laboratories’;
- ii. Increasing access to sophisticated reagents, such as standardised DNA ‘parts’ and easy-to-use commercial kits and services;
- iii. Web-based technologies that facilitate the transfer of tacit knowledge, through the emergence of formal and informal global learning communities and partnerships;
- iv. Barriers to the spread of science and technology knowledge for responsible, educational purposes are being reduced, creating more favourable conditions for international cooperation;
- v. But the same barriers also serve as impediments to misuse, and the risks involved need to be assessed and managed.

Risks and benefits of convergence

22. Convergence is expected to bring about huge benefits. Examples are the development of more effective, safer and cheaper medicines, including personalised treatments, and more effective and sustainable methods of food production and pest control. Biological methods and knowledge can also find application in other important fields, such as responding to the effects of global warming, the development of the information sciences, or the development of human-machine interfaces.

23. The same developments, however, can also increase the risk posed to the chemical and biological weapons arms control and security system. These risks could emanate from:

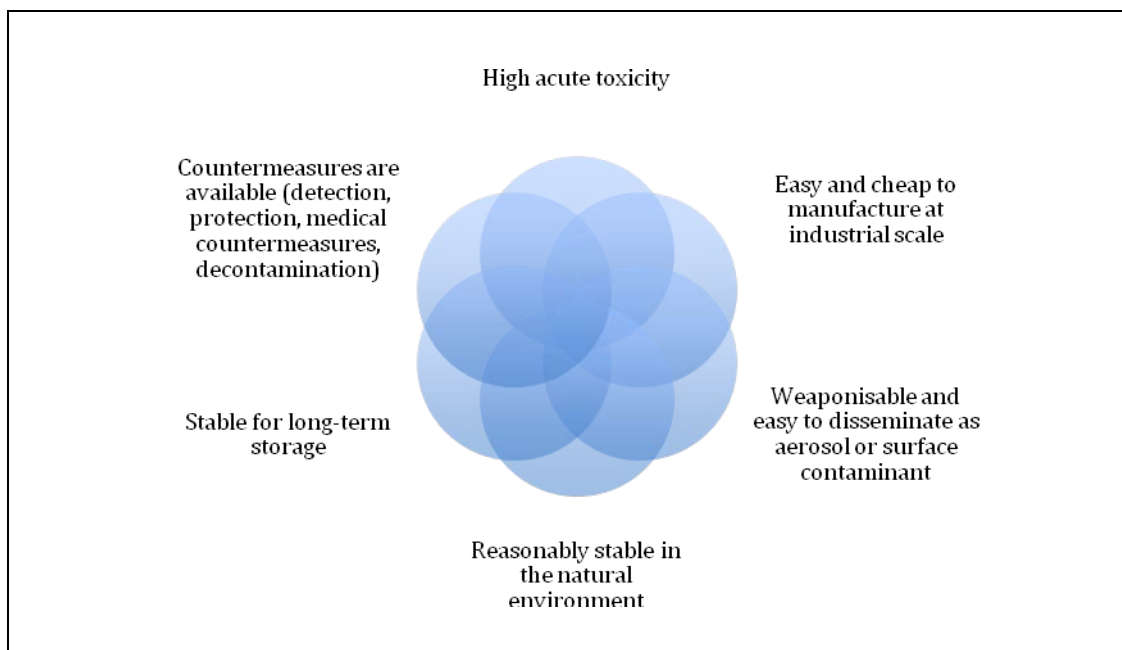
- i. The discovery of new candidate chemical or biological agents (either in the form of new agents with biological potency, or through new ways of selectively interfering with pathways or receptors);
- ii. The discovery of more sophisticated techniques for the dissemination/delivery of chemical and biological agents;
- iii. The development of new processes for the manufacturing of chemical and biological agents;
- iv. A wider diffusion of technologies, equipment and materials, thus inadvertently spreading the capability to manufacture known, as well as novel biological or chemical agents (by countries, criminal and terrorist organisations, or individuals).

In order to devise appropriate risk management strategies, it is worthwhile taking a closer look at where the existing arms control and security systems may be particularly vulnerable.

Challenges to verification under the Chemical Weapons Convention

24. The Chemical Weapons Convention's verification system has been designed with the experience of past chemical weapons programmes in mind. These programmes have screened thousands of chemicals for their utility as chemical weapons, in order to find agents that meet the criteria for military use. Amongst the hundreds of thousands of toxic chemicals that exist, only a surprisingly small number met these criteria and were adopted by military programmes (Box 9.5). These include nerve agents, blister agents, and several other groups of agents.²²

Box 9.5: How toxic chemicals are selected in military programmes.



25. These past chemical weapons programmes are mirrored in the Convention's 'Schedules' – lists which contain toxic as well as precursor chemicals known from past chemical weapons programmes, that have been selected for the purposes of verification, including in the chemical industry. In some cases, entire groups of chemically related compounds have been included, in order to provide extra assurance. The Schedules trigger declarations of production activities and facilities by States Parties, on-site inspections in the chemical industry, and national controls to prevent transfers of these chemicals for chemical weapons purposes.

26. The Convention also contains provisions for the declaration and inspection of 'Other Chemical Production Facilities' – these are chemical plants producing discrete organic chemicals not listed in the Schedules. This was necessary because the chemicals included in the Schedules do not reflect all synthetic routes to chemical weapons, but only those of particular relevance for industrial-scale production. The provisions relating to these additional production facilities also provide some verification of other chemicals that could be used for chemical weapons purposes.

27. This verification regime for 'Other Chemical Production Facilities' lacks focus: the specific chemicals are not identified, and there are thousands of such plants in operation worldwide. How can this non-specific, "spot-check"-like verification

system take account of new toxic chemicals with possible warfare potential (for example, certain bioregulators and peptides²³), or new synthetic methods suitable for manufacturing chemical weapons? In principle, there are three options:

- i. Adding new chemicals to the Schedules;
- ii. Adding more precision to the verification system for Other Chemical Production Facilities, to make it easier to select for inspection those chemical plants that are of higher relevance;
- iii. Creating new verification systems for additional types of chemicals that are considered to pose particular risks.

28. Whether the States Parties of the Chemical Weapons Convention are prepared to take such steps depends on many considerations – not only their impact on preventing development of new chemical weapons, but also economic factors such as the impact of new verification provisions on industry and trade, the associated costs for domestic implementation and international verification, and political factors.

Challenges to implementation of the Biological and Toxin Weapons Convention

29. The challenges posed by convergence to the biological arms control regime are essentially in the area of national implementation. In the absence of international verification measures, assurance of compliance falls to consultative processes among the States Parties and, at the domestic level, to the measures that States Parties take to prevent the development, production and use of biological and toxin agents for hostile purposes.

30. At the international level, managing the risks of convergence requires an effective mechanism for reviewing what is happening in science and technology, and how that affects the BTWC, as well as robust mechanisms to resolve any disputes between States Parties. To facilitate the review of science and technology, States Parties have made it a standing agenda item of their intersessional meetings. The Implementation Support Unit regularly reports on such advances, some States Parties also prepare their own reviews, and the Review Conferences regularly deal with this matter. Problems do not emanate from a lack of procedure, but from difficulties in evaluating

exactly what these advances mean. States Parties often find it hard to address activities that they consider legitimate in their own case, but which they might regard as suspicious if conducted by others. Compliance is a political and legal judgement rather than a scientific one, and translating technical evaluations into political conclusions on a collective basis by all States Parties is often difficult.

31. On the practical side, convergence is changing the scientific and industrial landscape in the biological field. That has implications for how States Parties meet their obligation to prevent the misuse of biology for hostile purposes. The questions they need to ask themselves include:

- i. Should laws regulating the production, trade and use of biological materials be changed, or are new laws required?
- ii. Are additional administrative measures (such as licensing of facilities, activities or individuals) necessary and appropriate?
- iii. Should new materials, equipment and technologies be made subject to export controls?
- iv. But also, how would such new regulatory measures affect science, the development of technology, industry and trade?
- v. And if new regulations appear undesirable, what else can be done to manage the risks associated with these new technologies?

Challenges to underlying assumptions

32. Convergence also affects the context within which measures to ensure security and treaty compliance are applied. A recent study observed: “The farther the distance in time grows from the chemical and biological weapons programmes of the Cold War area, the more one must ask what a novel chemical or biological weapon might look like. Would risk evaluation actually recognise the intended use of certain chemical or, perhaps more importantly, biological agents? What would a new biochemical weapons programmes look like? [And] what would be the aim of such a future chemical or biological weapons programme? Would it aim at the acquisition of a weapon of mass destruction as in the past, or (more likely) the acquisition and use of chemical or biological agents in smaller amounts for other purposes (terror,

destabilisation, manipulation), in ways that make it easier for a perpetrator to deny responsibility for the attack?”²⁴

33. These are difficult questions, but they are not altogether new. What has changed is the environment within which answers need to be found. How can technology development be directed in such ways that risks can be managed, and what actions should the different actors (international organisations, governments, industry, science community) take?

Managing the risks of convergence

34. In the past, managing security risks was predominantly top-down and government-centric, involving legislation, regulations, control measures such as export licensing, and inspections by national enforcement bodies, and sometimes by international agencies. Such measures will remain necessary, but we need to recognise that we are increasingly living in a world where scientific knowledge, technology and manufacturing capacities are globally distributed. Preventive strategies, that build on concepts of denial of access to technology and control over access to materials and equipment, lose both effectiveness and justification in a context where science and technology are globally distributed and their benefits globally harnessed. The question today is not whether regulatory and administrative measures are necessary, but how regulations can be complemented by effective risk management strategies, that ensure that the development, trade and legitimate uses of chemistry and biology are not obstructed.

35. In this changing world, top-down actions alone will increasingly become inadequate. For example, “there are limitations to the effectiveness of governmental mechanisms to review S&T impact. Even in areas of science that directly affect arms control, governmental science advisory structures are not necessarily well connected with the front edge of the scientific enterprise. Also, when it comes to finding answers to emerging threats, the response often requires governance efforts within the science, technology, and industry communities, in addition to any necessary changes in the law.”²⁵

36. Governments are no longer the primary users, producers and funders of research in the life sciences. Strong drivers emanate from the markets and from within the research and industry communities themselves. Furthermore, many of the measures required to prevent misuse will require the active participation of these communities in the development and application of preventive strategies. This requires awareness in the science and industry communities of the need to embed these preventive principles into their self-image and professional ethics.

37. An example for this move from ‘governments’ to ‘governance’²⁶ is the chemical industry’s involvement with the Chemical Weapons Convention. It started during the mid-1980s, when the industry realised that the negotiations were making headway towards agreeing the Convention. As McLeish and Lak noted, “industry’s involvement was not for purely altruistic reasons. Factors influencing their decision to become involved included: public perception issues which saw the chemical industry associated with pollution and disaster; industry’s linkages to the chemicals used in the Vietnam War such as Agent Orange; the growing realization that governments were committed to negotiating a comprehensive and global convention; and the fact that much of the precursor chemicals and equipment used by Iraq in its chemical weapons attacks against Iran had been supplied by industry.”²⁷ In subsequent years, the chemical industry followed closely the progress of the negotiations, submitted proposals on how the industry verification system could be shaped, and even participated directly in the negotiations (see Box 9.6). During the work of the Preparatory Commission, the chemical industry supported the setting-up of the Organisation for the Prohibition of Chemical Weapons with technical advice and access to its training facilities, and it opened the doors of some of its plants for inspector training.

Box 9.6: The chemical industry and chemical weapons disarmament – a champion in industry. (Source: Laurie Skrivan, lskrivan@post-dispatch.com)



Dr Will Carpenter
PhD from Purdue University

Joined Monsanto in 1958 and retired 1992 as Vice President of its New Products Division.

From 1978 – 2003, he worked with the US State Department as chemical industry expert, supporting the negotiations and later the implementation of the Chemical Weapons Convention.

From 1979 - 1992, he was Chair of the United States' Chemical Manufacturers Association's Committee on the Chemical Weapons Treaty.

From 1998 – 2003, he served as Vice Chairman of the OPCW Scientific Advisory Board.

In 2013, the OPCW received the Nobel Peace Prize for its work towards global chemical weapons disarmament, which was also a recognition of the contribution by Will Carpenter and other supporters in industry of a chemical weapons ban.

38. More importantly, the industry began to internalise these requirements into its own mainstream initiatives. In 2003, the International Council of Chemical Associations, which represents chemical industry associations throughout the world, stated that its “support for the CWC is rooted in the chemical industry’s voluntary Responsible Care® initiative. The CWC is one of many important tools industry employs to help fulfil its commitment to Responsible Care® in the management of chemicals worldwide... Implementation of Responsible Care® is consistent with the CWC’s goals of fostering and furthering the peaceful use of chemistry and preventing the misuse of essential chemical products for making chemical weapons by developing and implementing effective safeguards on chemical products”.²⁸

39. The relationship between the pharmaceutical industry and the Biological and Toxin Weapons Convention has evolved in a more complicated way. Nevertheless, voluntary compliance measures, such as checks of customers and orders of certain products and services, have been incorporated into industry codes of conduct.²⁹

40. This shift from governments to governance brings its own benefits: greater interdependence, broader involvement, and increased transparency. To many governments, these may appear less robust than traditional government controls. But they are strong safeguards against the unpredictability of how and where exactly new life science discoveries will find practical application.

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Chapter 10: The role of scientific organisations in promoting biosecurity: a case study on the InterAcademy Panel

Jo Husbands and Katherine Bowman

Key learning objectives

- i. Understand several ways in which scientists operating through national and international networks can contribute to discussions on biological and chemical security topics;
- ii. Be able to discuss how the Biological and Toxin and Chemical Weapons Conventions have provided opportunities to engage scientists in considering ethical and security issues;
- iii. Be able to discuss how and why independent scientific input is important to the effective implementation of the Biological and Toxin and Chemical Weapons Conventions, drawing on material in this and other chapters.

Introduction

1. Mary Osborn, a well-known British cell biologist working at the Max Planck Institute in Göttingen, Germany, stood at the podium in one of the cavernous plenary halls of the Palais des Nations in Geneva. As President of the International Union of Biochemistry and Molecular Biology (IUBMB), she had been invited to give a talk at the 2005 Meeting of Experts of the Biological and Toxin Weapons Convention (BTWC), where the topic for that year's discussion was the "content, promulgation and adoption of codes of conduct for scientists."¹ The 400 plus people in the audience included diplomats from member states, other government officials, representatives from international and civil society organisations, and invited guests, including many from national and international scientific bodies. The experience had a significant impact on Dr. Osborn. As she described in her annual report: "Until 2005 IUBMB had no official code of ethics. The idea that such a code could be useful came from a

meeting in Geneva in which I participated on behalf of [the Union]. ... As the Chair of this meeting, John Freeman stated it as important that such meetings include the voice of scientists themselves. Listening to the meeting convinced me that [we] should develop an IUBMB Code of Ethics. A special committee... undertook this task. The draft code was sent to biochemists and molecular biologists from around the world who were asked to comment. The code, which covers ethical conduct of scientists at different levels, is posted on the [Union's] website.”²

2. Among the other speakers at the 2005 meeting was Sergio Pastrana, Foreign Secretary of the Cuban Academy of Sciences. Dr. Pastrana had come to present the draft of a Statement on Biosecurity, prepared by the Biosecurity Working Group of the Inter Academy Panel (IAP) – The Global Network of Science Academies. The IAP was created in 1993 to develop the capacity of its member academies to provide advice to governments and the public on critical global issues.³ The Biosecurity Working Group was created in 2004, in large part to take advantage of the opportunity offered by the 2005 BTWC meeting. Several national academies were already playing important roles in advising their governments and encouraging scientists to become involved, but most of the voices promoting biosecurity as an issue were coming from governments. The 2005 meeting was the chance to gain support from organisations that scientists might listen to and trust. And the composition of the Working Group - the national academies of China, Cuba, Nigeria, the Netherlands (chair), the United Kingdom, and the United States - would give international credibility.

3. The final Statement on Biosecurity was released in December 2005, by which time it had the endorsement of 69 of the IAP's 94 members. The Statement, found in Box 10.1, covers 5 principles that the IAP believed should be included in any code of conduct: Awareness, Safety and Security, Education and Information, Accountability, and Oversight. The Biosecurity Working Group had concluded that the Statement's impact would be most powerful if it set out fundamental principles, but actual codes were developed at the national level or below, where more scientists could have a role in creating them and therefore feel a greater sense of ownership. For example, as a result of the Statement, the Dutch Government asked the Royal Netherlands Academy of Arts and Sciences to create a biosecurity code; more recently, the Netherlands

Academy has helped the Indonesian Academy of Sciences to develop its own code of ethics. The Statement was echoed in a 2012 report from the IAP and its counterpart organisation, the InterAcademy Council: Responsible Conduct in the Global Research Enterprise. Like the Biochemistry Union's Code of Ethics, the report from the inter-academy networks treats biosecurity as part of the broader social responsibilities of scientists, concluding that "Researchers should bear in mind the possible consequences of their work, including harmful consequences, in planning research projects."⁴

Box 10.1: The IAP statement on biosecurity.

In recent decades scientific research has created new and unexpected knowledge and technologies that offer unprecedented opportunities to improve human and animal health and environmental conditions. But some science and technology can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of "dual use" and the misuse of science and technology.

The 1972 Biological and Toxin Weapons Convention reinforced the international norm prohibiting biological weapons, stating in its provisions that: "Each state party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: 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 or other peaceful purposes." Nevertheless, the threat from biological weapons is again a live issue. This statement presents principles to guide individual scientists and local scientific communities that may wish to define a code of conduct for their own use.

These principles represent fundamental issues that should be taken into account when formulating codes of conduct. They are not intended to be a comprehensive list of considerations.

1. Awareness. Scientists have an obligation to do no harm. They should always take into consideration the reasonably foreseeable consequences of their own activities.

They should therefore:

- i. always bear in mind the potential consequences – possibly harmful – of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavour;
 - ii. refuse to undertake research that has only harmful consequences for humankind.
2. Safety and Security. Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or common practice.
3. Education and Information. Scientists should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research.
4. Accountability. Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies.
5. Oversight. Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation and act as role models in this regard.

4. The value of engaging scientists in considering the potential biosecurity implications from their research, and of encouraging them to conduct their studies responsibly, has not been a one-time discussion, held only at the 2005 BTWC meeting. One of the topics discussed during the Convention's 2008 meeting, for example, was "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."⁵ A number of international scientific organisations were again invited to make formal presentations to the plenary sessions of the meeting. There were also chances for informal sessions and personal interactions. All of these provided opportunities for scientists and scientific

organisations to interact with the international diplomatic and security community about topics that were directly relevant to their interests. (See also Box 10.2.)

Box 10.2: Structure and activities of scientific organisations.

The global scientific community includes a wide array of national and international organisations in multiple disciplines, along with an enormous number of ad hoc and informal collaborations among researchers to tackle specific scientific questions or to address the development of key tools and infrastructure needed by a field. The community includes:

1. Individual members, including practising researchers, other scientific professionals, postdoctoral fellows, and undergraduate and graduate students, working in academia, industry, non-profit, and government sectors.

2. National bodies, such as academies of science, which often include distinguished members elected for their research achievements. Academies of science may be active in advising their governments on critical social and policy issues.

3. Associations of scientists in particular fields and subfields, such as professional societies at which scientists present their latest research. Because science is a global enterprise, the membership of many scientific societies is international in scope.

4. International umbrella bodies whose missions include strengthening the scientific enterprise, facilitating cooperation among scientists, and serving as sources of independent advice on critical global issues. International networks provide advice on specific topics, such as the Intergovernmental Panel on Climate Change, advance the contributions of particular fields of science (e.g., International Union of Pure and Applied Chemistry, International Union of Microbiological Societies), and consider needs across the scientific enterprise broadly (e.g., global networks of national academies of science, International Council for Science).

Many of the leaders of such scientific bodies are senior scientists; however, there is increasing interest in engaging younger scientists in discussions of issues at the intersection of science and policy. The Global Young Academy was established in 2010 to “empower and mobilize young scientists to address issues of particular importance to early career scientists.”⁶ Scientific associations and science unions also

frequently include younger scientist committees or chapters, feature special young scientist programmes at international conferences, or provide travel and training support to foster the next generation of science leaders.

The examples in this chapter show how scientists can engage in biosecurity discussions at all of these levels. A global framework, such as the IAP, is particularly useful when addressing a multinational body, such as the BTWC, because it provides a mechanism to draw contributions from scientific experts in many regions. The IAP's activities in support of responsible science have also stimulated efforts by its national member academies to engage professionals and students in their own countries. Finally, all activities ultimately rely on the engagement of individuals. Individuals may serve as speakers or poster presenters at national and international workshops and forums. Individuals are also crucial contributors by promoting the norms of responsible conduct in their own projects and laboratories.



Young Observers from several countries participated in the 2013 business and scientific meetings of the International Union of Pure and Applied Chemistry in Turkey and shared their experiences on YouTube

(https://www.youtube.com/watch?feature=player_embedded&v=g_yFZeqcTgo). The Young Observers programme provides the opportunity for junior scientists from academia and industry to become more actively involved in the Union's programmes. The 2014-2015 president of the union, Dr. Mark Cesa, is a former Young Observer from the United States. Video Credit: Thao Nguyen Nguyen and IUPAC Young Observers 2013.

5. The stories told above illustrate the importance of providing opportunities to bring scientists into discussions on biosecurity policy, and the impact that these conversations can have. They also illustrate that discussions on codes of ethics, conduct, and practice can be an important tool for engaging scientists, and for

reinforcing a culture of responsibility within the scientific community. Codes developed by scientific organisations reflect the important tradition of self-governance in order to maintain responsible conduct in scientific research, and they provide part of the foundation for scientists to respond to societal concerns. More broadly, there are several different types of codes, and each one serves a different purpose; for example:

1. Aspirational codes (often designated as ‘codes of ethics’) set out ideals that practitioners should uphold, such as standards of research integrity, honesty, or objectivity. ...
2. Educational/Advisory codes (often designated as ‘codes of conduct’) would go further than merely setting aspirations, by providing guidelines suggesting how to act appropriately. ...
3. Enforceable codes (often designated as ‘codes of practice’) seek to further codify what is regarded as acceptable behaviour. Rather than inspiring or educating in the hopes of securing certain outcomes, enforceable codes are embedded within wider systems of professional or legal regulation.⁷

Given the important role that scientists play in biosecurity and the number of key sectors in which they work (for example, academia, industry, public health, and government), a scientist may encounter all types of codes in the course of his or her career.

Beyond codes: education and engagement of scientists

6. As discussed throughout this book, the education of scientists on biosecurity topics and their engagement in discussions of the implications of biosecurity concerns, involves more than codes of conduct. The IAP Working Group, in addition to the 2005 statement, organised conferences on biosecurity in 2005⁸ and 2008⁹ to discuss these broader issues. Each forum took place in the spring before the BTWC Meeting of Experts, and served as an important convening mechanism to help prepare for the meetings, to share information among individuals and groups working on issues raised by dual-use research¹⁰, and to encourage scientific organisations to become more active on science policy issues such as biosecurity. Both meetings were held in cooperation with other international scientific bodies - the International Council for

Science, the InterAcademy Medical Panel, and several international scientific unions. During the 2008 conference, hosted by the Hungarian Academy of Sciences, the participants discussed the challenges and opportunities for building a culture of responsibility within the science community regarding biosecurity, identifying standards and practices for research oversight, and developing the role of the science community in global governance. The working group on building a culture of responsibility focused most of its time on the question of how to effectively educate practising scientists and science students on biosecurity concerns and on issues posed by dual-use research.

7. In large part as a result of these activities, in 2008 the US State Department asked the IAP to convene a workshop to:

- i. survey strategies and resources available internationally for education on dual-use issues and identify gaps;
- ii. consider ideas for filling the gaps, including development of new educational materials and implementation of effective teaching methods; and
- iii. discuss approaches for including education on dual-use issues in the training of life scientists.¹¹

8. The workshop was organised collaboratively by several international scientific organisations. The Polish Academy of Sciences served as the host, and a planning committee with international membership was convened under the auspices of the US National Academy of Sciences. The meeting brought together researchers from the life sciences, specialists in bioethics and biosecurity, and, as one of the workshop's special features, experts in the science of learning. The workshop also discussed the similar challenges faced by any effort to introduce new educational material, such as the competition for space in an already crowded curriculum, or an academic reward structure that did not put high value on innovation or excellence in teaching. One clear message was "the importance of identifying and supporting 'champions' to the success of initiatives."¹² In addition, participants consistently cited the limited number of faculty and instructors sufficiently knowledgeable to teach about dual-use issues. This led to an extensive discussion of the importance of networks to support and sustain efforts to introduce new topics and new approaches. Examples of available materials that drew on research about effective teaching included online faculty

development courses from the University of Bradford in the United Kingdom, and World Health Organization train-the-trainer courses on biosafety and biosecurity, which had been redesigned to escape an older “death by PowerPoint” approach. The outcomes of the meeting led directly to the development of teaching institutes in the Middle East, North Africa, Southeast Asia, and other regions, described in Chapter 19.

9. By the end of 2014, the IAP Biosecurity Working Group had grown to 10 members, reflecting the diversity of international science; its members now include the national academies of Australia, China, Cuba, Egypt, India, Nigeria, Pakistan, Poland (the current chair), Russia, the United Kingdom and the United States. The IAP and the Working Group are actively engaged in highlighting the contributions of national academies to the full range of biosecurity policy. The activities range from the workshops and curriculum development projects that the Pakistan Academy has undertaken with universities throughout the country, to the watching brief that the Australian Academy maintains over dual-use export control policies that affect research and publication, to policy studies such as module on the security implications of developments in neuroscience from the United Kingdom’s academy of sciences (the Royal Society), which was cited by the UK Government in a background paper and presentations for the BTWC in 2012.¹³ One sign of recognition has been the number of representatives from national academies that are included in their country’s delegation to the annual BTWC Convention Meeting of Experts (Figure 10.1). As discussed in the next section, the IAP has had particular success in contributing to assessments of the implications of trends in science and technology for international security.

Figure 10.1: Individual scientists and scientific organisations participate in meetings of the Biological and Toxin Weapons Convention, held at the United Nations in Geneva, Switzerland.

A. Dr. Indira Nath (receiving flowers) spoke to the 2007 Review Conference on responsible scientific conduct. Seated is Dr. Esther Ng, who read her essay on the role of young scientists in addressing biosecurity concerns (see Chapter 11).

B. Professor Andrzej Gorski, Vice President of the Polish Academy of Sciences, reads a statement on behalf of the IAP Biosecurity Working Group. Photo Credits: Courtesy of Richard Guthrie.

A:



B:



Engaging scientists in discussions of trends in science and technology

10. Other chapters in this book describe advances in science and technology that are fuelling concerns for biosecurity. For the rest of this chapter the focus will be on how scientists can contribute as scientists to addressing biosecurity risks. As described in Box 10.3, sometimes scientists work with colleagues across political barriers to advance ideas for technical measures to support arms control and disarmament. More broadly, in fields advancing as rapidly as the life sciences, even governments with extensive resources of their own will have trouble keeping up with everything going on and what it means for biosecurity. There is just too much science being done in a growing number of subjects in an increasing number of parts of the world for anyone to effectively track the trends. The scope, pace, and diffusion of scientific capacity is great news for the hopes being placed in biotechnology to solve major global challenges. But it can sometimes resemble a tsunami, beyond anyone's capacity to comprehend. This matters because, beyond this essential monitoring function, policy

makers want to know what the advances mean. They need help in assessing the implications for biosecurity policy and practice. Scientists can help with both monitoring and assessing and, by engaging in this process, scientists become part of the solution, not part of the problem. Translating those insights for diplomats and policy makers, who generally lack technical backgrounds, is an important part of the overall challenge and requires expertise from beyond the life sciences.

Box 10.3: Scientists working across political and ideological boundaries.

“At a time when science plays such a powerful role in the life of society, when the destiny of the whole of mankind may hinge on the results of scientific research, it is incumbent on all scientists to be fully conscious of that role, and conduct themselves accordingly. I appeal to my fellow scientists to remember their responsibility to humanity.”

- Joseph Rotblat, Nobel Peace Prize Lecture 1995

In the course of doing their research, scientists make connections with colleagues based on shared interests, and build relationships that transcend national and political boundaries. The quality of one's science is the standard of judgment, not ideology. On occasion, this enables scientists to tackle problems that governments cannot. From the early days of the Cold War, for example, scientists from the United States and the Soviet Union worked together to find ways to reduce the risks posed by growing arsenals of nuclear weapons. One prominent group, the Pugwash Conferences on Science and World Affairs, shared the 1995 Nobel Peace Prize with their secretary general, physicist Joseph Rotblat, for this work. The group also worked to reduce the threat of chemical and biological warfare. Beginning in 1959, a series of workshops evolved in parallel with the international efforts to address these risks, playing important roles in the creation of both the BTWC and the Chemical Weapons Convention. The meetings provided venues where technical experts from governments and civil society could explore and debate ideas, many of which found their way into more formal policy discussions and actions. Once the Chemical Weapons Convention was signed in 1993, the Pugwash Study Group on the Implementation of Chemical and Biological and Toxin Weapons Conventions was set up to work toward the effective implementation of the two disarmament treaties. The Study Group held more than 30 meetings over the next two decades. In this case, scientists worked with experts in international law and politics, an example of the critical interactions between technical problems and policy.



Joseph Rotblat, a physicist and former secretary-general of Pugwash, was committed to the idea that scientists needed to consider the implications of their research. He resigned from working on the Manhattan project and remained a prominent supporter of nuclear disarmament.

Photo Credit: Courtesy of Pugwash Conferences on Science and World Affairs

11. Inter-academy networks like the IAP have been an important vehicle for the contributions of life scientists to biosecurity policy, but the story begins earlier. Around 2000, as preparations began for the Chemical Weapons Convention's (CWC) first Review Conference, the organisation that administers the treaty (the Organisation for the Prohibition of Chemical Weapons (OPCW)) realised that it would benefit from the input and insights that could be provided by the broader chemical sciences community. Fortunately, this organisation already had a relationship with the International Union of Pure and Applied Chemistry (IUPAC- the "Chemistry Union"- which was asked to organise a meeting on developments in chemical sciences and technology that could affect the future implementation of the Convention.¹⁴ The Scientific Advisory Board for the CWC wanted advice about emerging threats and about new developments that could support the Convention's missions. This was the first time that an international scientific organisation had been asked to provide input to a disarmament treaty review conference. Given its relatively limited resources, the Chemistry Union asked one of its national members, the US National Academy of Sciences, to help support the planning committee that it created to organise the workshop.

12. The workshop, held in Norway in 2002, brought together 79 participants from 34 countries, and set a number of precedents for how such events are best organised. The meeting combined researchers from academia and industry who were active in fields relevant to the CWC, with government technical experts, many of whom were also practising scientists. The researchers largely were asked to talk about their work, while the implications for the Convention emerged from the discussions and interactions with the policy and security specialists. This made it easier to interest the outside scientists in taking part, since they could do something they were familiar with doing—give a technical presentation about their work—while getting to think about their work in new ways. It was also an opportunity to bring younger scientists into the process; when a field is advancing rapidly, a number of breakthroughs may be made by emerging leaders in research. The discussions encouraged the researchers to consider key hurdles or barriers, both technical and conceptual, which might need to be overcome for a technology to reach fruition or achieve a major breakthrough. This can help bring a dose of reality to claims that may sometimes be exaggerated in the excitement of a scientific moment. Finally, the results were provided to the CWC via its Scientific Advisory Board and published by IUPAC, so that they were available both to officials and a broader interested public.¹⁵

13. When the time came for the Second and Third CWC Review Conferences, the OPCW again reached out to the Chemistry Union, which organised similar international workshops in Croatia (2007) and Switzerland (2012).^{16,17} One of the lessons that had been learned from the first workshop was the importance of starting early, so that the results could feed into preparations by national governments for the Review Conferences. The later workshops were therefore held a full year in advance of the Second and Third CWC Review Conferences, which meant that the reports could be given to the OPCW's Scientific Advisory Board in time to inform its own technical reports to member nations.

14. The success of the chemical science community's involvement in discussions for the CWC inspired people interested in biosecurity to consider doing the same thing to support the BTWC's Review Conferences. However, providing input from the broader biological sciences community to the Convention was a more complicated problem in this instance. As discussed in Chapters 6, 7, 9 and 11, the BTWC's

structure is different from the CWC's. In addition, instead of a single predominant International Union for Chemistry, there are perhaps a dozen international unions in the life sciences, reflecting the diversity and fragmentation of the field. Who would take the lead? This provided another opportunity for the IAP Biosecurity Working Group.

15. The IAP first convened an international workshop on developments in science relevant to the BTWC in 2006, to provide input to the treaty's Sixth Review Conference. The report of the meeting, prepared by the Royal Society, was provided directly to the diplomatic missions in Geneva that participate in the BTWC meetings. The Royal Society also organized an event at the Review Conference to describe the results to those taking part.¹⁸

16. The IAP's greatest success to date came in conjunction with preparations for the Seventh BTWC Review Conference. The workshop was hosted by the Chinese Academy of Sciences, and the report was produced by the US National Academy of Sciences. Through good fortune and planning, it was held at the same time as a conference organised by the Chinese and Canadian Governments that addressed the range of issues that would come up in the Review Conference. A number of government technical experts who attended the science and technology-focused workshop were able to stay for the Chinese-Canadian event, which increased their representation at the meeting. The IAP was also represented as an invited guest. Abstracts of the presentations were produced in time for the treaty's Preparatory Committee meeting in April 2011, and the final report was released during a side event at the United Nations in October.¹⁹ The report was organised around three themes, which can be found in many of the chapters in this textbook:

- i. The rapid pace of change in the life sciences and related fields;
- ii. The increasing diffusion of life sciences research capacity and its applications, both internationally and beyond traditional research institutions; and
- iii. The extent to which additional scientific and technical disciplines beyond biology are increasingly involved in life sciences research.²⁰

17. As a testament to the relationships that the IAP Working Group had built through its scientific workshops and other efforts, the Implementation Support Unit for the BTWC included the summary of the workshop's final report as part of the official background document on science and technology produced for the Seventh Review Conference.²¹ The chair of the organising committee for the workshop was also invited to serve as a member of a Temporary Working Group on the convergence of chemistry and biology, organised by the Scientific Advisory Board for the CWC (see Chapter 9 for further discussion of this convergence).²²

18. As with the workshops held to inform the CWC, those for the BTWC bring together practising scientists from academia and industry, scientific and technical members of national delegations, and policy and security experts. Participants are drawn from a number of countries and organisations, reflecting the fact that advances in science come from multiple disciplines, and that the life sciences community is global. An IAP member academy of science usually serves as the host; past workshops have involved collaborative partnerships with international unions in biochemistry, molecular biology, and microbiology, and umbrella organisations such as the International Council for Science, to which most of the relevant life sciences unions belong. Workshop sessions mix plenary presentations with small-group discussions on how scientific and technical developments can benefit the Convention's implementation, such as through improved disease surveillance and treatment; whether new developments could pose potential risks for misuse in ways contrary to the Convention; drivers moving science forward; and technical hurdles that remain to be overcome. Links are also maintained across efforts to inform the CWC and BTWC, to enable themes and technical issues to be carried over between workshops. A timeline showing examples of activities that have been undertaken by international scientific networks to contribute to biological and chemical security discussions is shown in Figure 10.2; photographs of several of the workshops are provided in Figure 10.3.

Figure 10.2: Engagement of international scientific networks in biosecurity: a timeline of selected activities.

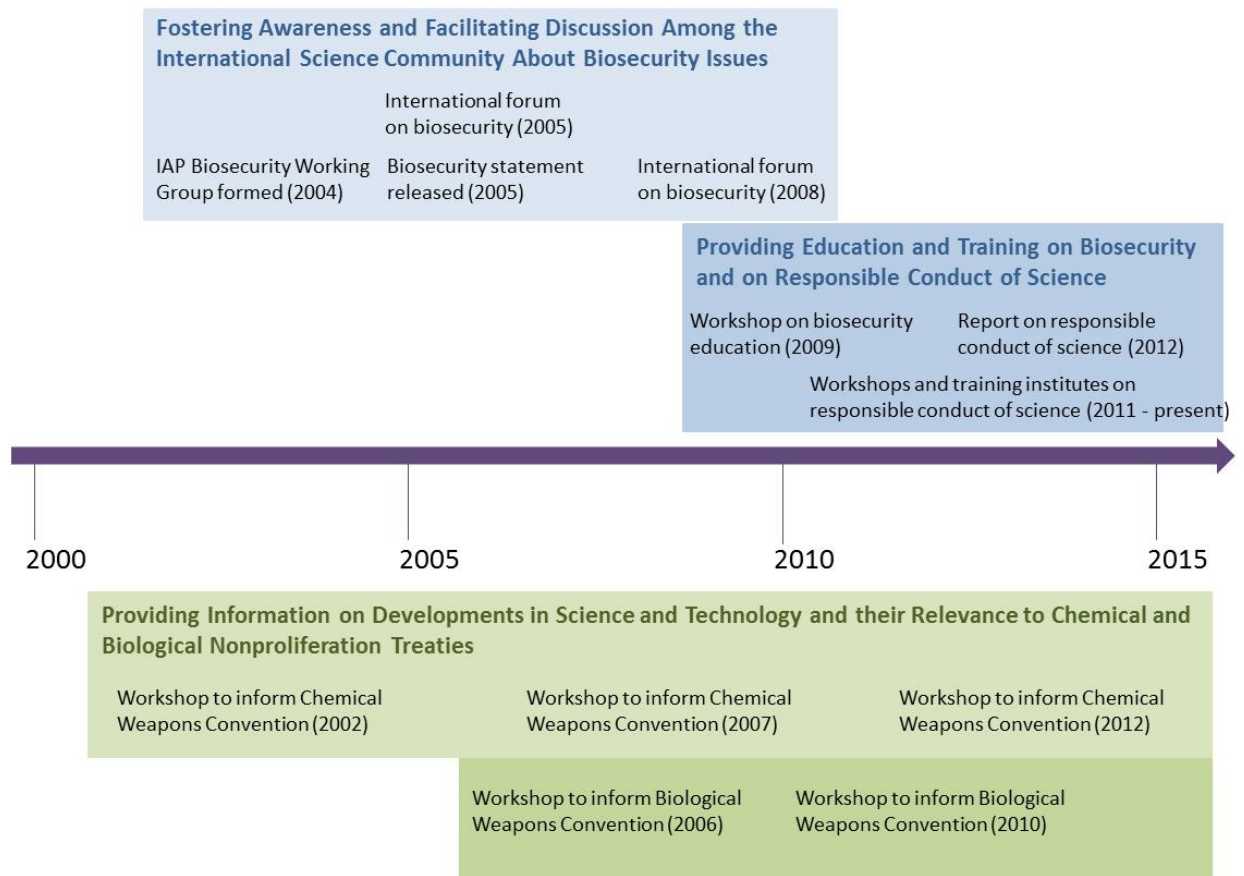


Figure 10.3: Scientific, technical, and policy experts interested in biosecurity issues engage in discussions on recent developments and their potential implications for the Biological and Toxin and Chemical Weapons Conventions.

A and B. Workshops held in Croatia (2007) and Switzerland (2012).

C and D. A working group discussion and plenary session from a workshop held in China (2010).

Photo Credits: A. Courtesy of Danko Skare, Institut Ruđer Bošković; B. Courtesy of Patrick John Y. Lim, University of San Carlos Press; C. and D. Courtesy of Qiang Wang, Institute of Biophysics, Chinese Academy of Sciences.

A.



B.



C.



D.



19. These events and their impacts have created what can be considered an “informal science advising network” from the scientific community, via national and international scientific organisations, to the BTWC and CWC. The community, including the IAP, member academies of science, industry organisations, and individual scientists, has made increasing numbers of contributions to BTWC meetings (see Table 10.1, which shows selected contributions since 2012). As States Parties look ahead to the Eighth BTWC Review Conference in 2016, discussions

continue on whether a systematic process is needed to inform the Convention of relevant scientific developments and their implications. Whatever process may be chosen, contributions from the broader scientific community will likely continue to have a role in understanding research advances. For anyone interested in how scientists and scientific organisations can become involved in science policy, particularly at the international level, it is worth wading through the sea of organisational acronyms to explore the case of the IAP and its international partners.

Table 10.1: Selected contributions made by individuals, universities, international scientific organisations, and industry to recent meetings of the Biological and Toxin Weapons Convention.

Person or Organisation	BWC Meeting	Title
Kenneth Oye, Massachusetts Institute of Technology	2014 Meeting of Experts	Presentation to the Meeting: “On Regulating Gene Drives A New Technology for Engineering Populations in the Wild”
Sonia Pagliusi, Developing Countries Vaccine Manufacturers Network	2014 Meeting of Experts	Presentation to the Meeting: “Developing Countries Vaccine Manufacturers Network : Improving vaccination for all people”
US National Academy of Sciences, IAP, and King’s College London	2014 Meeting of Experts	Side Event: Developments in Science & Technology Relevant to the BWC
OPCW and University of Hamburg	2014 Meeting of States Parties	Side Event: Innovative and Enabling Technologies: Embracing Developments in S&T to Benefit Treaty Implementation
Sung-Woo Kim, Nanobiosys	2013 Meeting of Experts	Presentation to the Meeting: “Application of LabChip System for Quantitative Detection of Biological Pathogens”
Wolfgang Laux, Sanofi	2013 Meeting	Presentation to the Meeting: “The

	of Experts	Semi-Synthetic Artemisinin Project Industrialization of a Synthetic Biology Derived Product”
Indonesian Academy of Sciences and Royal Netherlands Academy of Arts and Sciences	2013 Meeting of Experts	Side Event: Dealing with Dual Use Research of Concern
Bradford University, US National Academy of Sciences, and Landau Network – Centro Volta	2013 Meeting of Experts	Side Event: Dual Use Education
Royal Netherlands Academy of Arts and Sciences	2013 Meeting of States Parties	Side Event: Improving Biosecurity - Assessment of Dual Use Research
Andrew Pitt, Aston University	2012 Meeting of Experts	Presentation to the Meeting: “Potential Advances in Technologies in the Life Sciences”
Marcus Graf, International Gene Synthesis Consortium	2012 Meeting of Experts	Presentation to the Meeting: “Synthetic Biology: Biosecurity in a Rapidly Emerging Field”
IAP and International Union of Biochemistry and Molecular Biology	2012 Meeting of Experts	Side Event: Recent Developments in Science and Technology

Reference

¹ A wealth of information on the Biological Weapons Convention and its activities is available from the United Nation’s website at <http://www.unog.ch/bwc>. More information about the 2005 Biological Weapons Convention meeting may be found at [http://www.unog.ch/80256EE600585943/\(httpPages\)/DA292636AE31F1CBC125718600361E55?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/DA292636AE31F1CBC125718600361E55?OpenDocument) (accessed 16 June 2015).

² International Union of Biochemistry and Molecular Biology (IUBMB), ‘Report of the President,’ *Annual Report 2005* (no page number), <http://www.iubmb.org/index.php?id=41> (accessed 16 June 2015) and *Code of Ethics of the International Union of Biochemistry and Molecular Biology*, 2005, <http://www.iubmb.org/index.php?id=155> (accessed 16 June 2015). Among the “Obligations to the Public” described in the code for the union’s members is that “They will not engage knowingly in research that is intended for the production of agents of biological warfare or bioterrorism, nor promote such agents.”

³ More information about IAP, which was originally called the InterAcademy Panel on International Issues, may be found at <http://www.interacademies.net>.

⁴ InterAcademy Council and InterAcademy Panel, *Responsible Conduct in the Global Research Enterprise*, Amsterdam: IAC, 2012, p.16.

⁵ Information about the 2008 Biological Weapons Convention meeting may be found at [http://www.unog.ch/80256EE600585943/\(httpPages\)/8C24E93C19BDC8C4C12574F60031809F?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/8C24E93C19BDC8C4C12574F60031809F?OpenDocument) (accessed 16 June 2015).

⁶ Information on the Global Young Academy and its activities is available at <http://www.globalyoungacademy.net/> (accessed 16 June 2015).

⁷ Rappert, Brian, *Towards a Life Sciences Code: Countering the Threats from Biological Weapons*, Bradford Briefing Papers (2nd Series), No. 13, Bradford, UK: University of Bradford, 2004, p.14; 17.

⁸ There is no report of the first conference, but the agenda and participants list may be found at <http://nas-sites.org/biosecurity/international/> under the heading “International Forums on Biosecurity” (accessed 16 June 2015). The IAP draft statement was discussed extensively during the small group session on codes of conduct, for example, and revised in response to the comments and suggestions.

⁹ National Research Council, *2nd International Forum on Biosecurity: Report of an International Meeting, Budapest, Hungary, March 30-April 2, 2008*, Washington, DC: National Academies Press, 2009.

¹⁰ Dual use research in the biological sciences refers to the fact that “the same technologies can be used legitimately for human betterment and misused for bioterrorism” (National Research Council, *Biotechnology Research in an Age of Terrorism*, Washington, DC: National Academies Press, 2003, p.1). The US National Science Advisory Board on Biosecurity (NSABB) has further defined dual use research of concern as “research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security”, <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern> (accessed 16 June 2015).

¹¹ National Research Council, *Challenges and Opportunities for Education about Dual Use Issues in the Life Sciences*, Washington, DC: National Academies Press, 2011.

¹² *Ibid.*, page 87.

¹³ Further information about the activities of the IAP Biosecurity Working Group’s member academies may be found on its webpage at <http://www.iapbwg.pan.pl/> (accessed 16 June 2015).

¹⁴ For more information about the relationship that has developed between the International Union of Pure and Applied Chemistry (IUPAC) and the Chemical Weapons Convention, see Organisation for the Prohibition of Chemical Weapons, *Education and Engagement: Promoting a Culture of Responsible Chemistry*, Final Report of the Scientific Advisory Board’s Temporary Working Group, The Hague, Netherlands: Organisation for the Prohibition of Chemical Weapons, 2014, http://www.opcw.org/index.php?eID=dam_frontend_push&docID=18014 (accessed 16 June 2015).

¹⁵ The results of the first workshop were published as a special issue of the IUPAC journal, *Pure and Applied Chemistry*, 74:12 (2002), pp. 2229-2353, <http://www.iupac.org/publications/pac/74/12/> (accessed 16 June 2015).

¹⁶ Balali-Mood, Mahdi et al., ‘Impact of scientific developments on the Chemical Weapons Convention (IUPAC Technical Report),’ *Pure and Applied Chemistry*, 80:1 (2008), pp.175-200.

¹⁷ Smallwood, Katie et al., ‘Impact of scientific developments on the Chemical Weapons Convention (IUPAC Technical Report),’ *Pure and Applied Chemistry*, 85:4 (2013): pp. 851–881, <http://www.iupac.org/publications/pac/85/4/0851/> (accessed 16 June 2015).

¹⁸ The Royal Society, *Report of the RS-IAP-ICSU international workshop on science and technology developments relevant to the Biological and Toxin Weapons Convention*, RS policy document 38(06), London, UK: Royal Society, 2006, https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2006/8245.pdf (accessed 16 June 2015).

¹⁹ For summaries of the workshop presentations, see National Research Council, *Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention: Summary of an International Workshop: October 31 to November 3, 2010, Beijing, China*. Washington, DC: National Academies Press, 2011. The final report, from which the summary provided to the Biological Weapons Convention was taken, is National Research Council, *Life Sciences and Related Fields: Trends Relevant to the Biological Weapons Convention*. Washington, DC: National Academies Press, 2011, http://www.nap.edu/openbook.php?record_id=13130 (accessed 16 June 2015).

²⁰ *Ibid.*, page 4.

²¹ Implementation Support Unit, *New scientific and technological developments relevant to the Convention*—Background information document submitted by the Implementation Support Unit, BWC/CONF.VII/INF.3, [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/E8E780F95338D5C5C1257927004C2D07/\\$file/Background-+S&T.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/E8E780F95338D5C5C1257927004C2D07/$file/Background-+S&T.pdf) (accessed 16 June 2015).

²² Organisation for the Prohibition of Chemical Weapons, *Convergence of Chemistry and Biology*, Report of the Scientific Advisory Board's Temporary Working Group, The Hague, Netherlands: Organisation for the Prohibition of Chemical Weapons, 2014, http://www.opcw.org/index.php?eID=dam_frontend_push&docID=17438 (accessed 16 June 2015). The deputy of the Biological Weapons Convention's Implementation Support Unit also served as a member of the temporary working group.

Chapter 11: Review of science and technology: a case study on the Biological and Toxin Weapons Convention Implementation Support Unit

Piers Millett

Key learning objectives

- i. Discuss how an international policy process identifies scientific and technological developments that might be of relevance;
- ii. Understand the obligations on different actors to help ensure developments in science and technology are not used to cause deliberate harm, in particular the role of scientists as part of responsible conduct;
- iii. Identify opportunities for scientists to contribute to the work of the Biological and Toxin Weapons Convention – both as channels of outreach and also to help shape international policy;
- iv. Understand the evolving nature of institutional arrangements to address this issue – both the need for support and the arrangements in place to service that need may change over time.

Introduction

1. Under the international regimes in place to deal with nuclear or chemical weapons, international organisations provide substantive support in implementing Convention obligations. In this chapter we address the Implementation Support Unit (ISU) for the Biological and Toxin Weapons Convention (BTWC), and consider the extent to which its functions have evolved in a relation to the annual review of developments in the field of science and technology; its role in reaching out to scientists and technologists;

its role in facilitating scientists in contributing to the BTWC, the evolution of the ISU; and future developments.

The Implementation Support Unit

The BTWC has no international organisation. Implementation remains the responsibility of individual countries. Instead, since August 2007, the BTWC has an ISU, also referred to as the Unit. The Unit does not provide substantive assistance, but rather acts as a central hub, facilitating communication amongst the community that supports the work of the Convention. Of particular relevance here, is the Unit's role as a conduit to facilitate the flow of information between the science and security communities.

2. Members of the ISU form the core of Secretariats of meetings of the BTWC.¹ They provide the Chairs and Vice-Chairs with substantive support and advice, oversee procedural components, and gather and process input from participants. They are at the end of a phone, fax or email to assist State Parties and deal with enquiries from international and non-governmental sources. The Unit acts as an institutional memory for the Convention, and helps shape the content and outcome of its processes. The unit also gathers data from State Parties, processes it, conducts basic analysis and distributes the information, via the restricted part of the Convention's website and in its annual report to the Meeting of States Parties (MSP).

3. Not all of the work of the ISU is done in Geneva. Increasingly, there is demand for the Unit to engage at a regional, sub-regional, national or sub-national level. For example, during the 2007-2010 intersessional work programme (ISP), the Unit participated in 135 events in 45 States in all regions of the world. These events allowed the Unit to interact with representatives of over 130 States. The Unit has played an important role in increasing awareness of the Convention and its provisions in policy, technical and public forums.

The role of the Biological and Toxin Weapons Convention Implementation Support Unit in reviewing science and technology

Review Conferences

4. Every five years member states convene a Review Conference. The work of each Review Conference is determined by its predecessor.² To date, they have all: opened with a general debate, where State Parties can make overarching statements; reviewed progress on an Article-by-Article basis; considered progress in reaching the purposes of the Convention more broadly; looked back on any ISP; and considered future reviews and any necessary intersessional work.³

5. Although no specific time is set aside for reviewing developments in science and technology, each Review Conference has instructed its successor to take them into account. As a result, relevant developments in science and technology are considered as part of the review of the Convention's first Article (on its scope).

6. State Parties may provide details of relevant developments in science and technology.⁴ Few countries, however, actually provide information (Figure 11.1). Initially, contributions were restricted to the Convention's three Depositories (Russia, the United Kingdom, and the United States). Since 1986, all countries have been able to provide their own reviews. Whilst the number of contributions is limited, the content can be comprehensive. For example, Table 11.1 illustrates the topics covered in the submissions from State Parties to the Seventh Review Conference in 2011.

Figure 11.1: State Parties submitting information to reviews of science and technology at successive Biological and Toxin Weapons Convention Review Conferences.

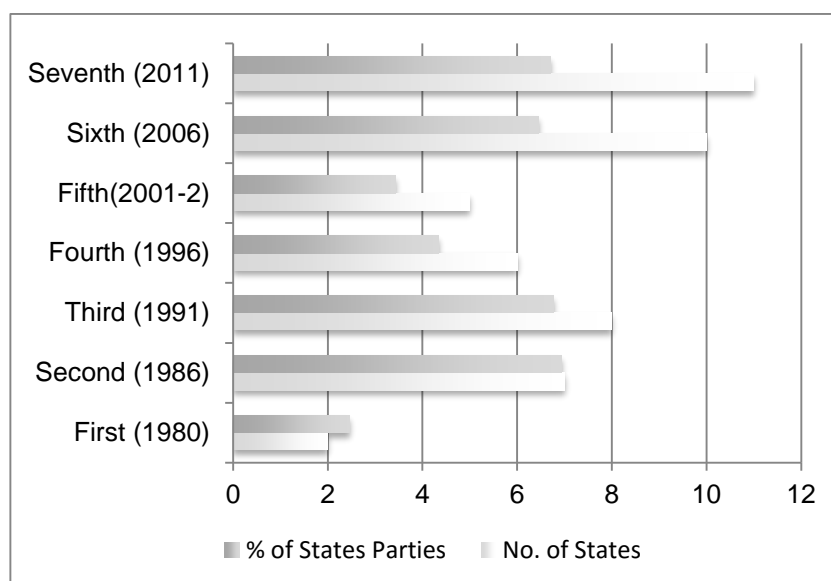


Table 11.1: Topics covered by State Parties' submissions on relevant developments in science and technology to the Biological and Toxin Weapons Convention 2011 Review Conference.

Topic	State(s)
Advances in manipulation of genetic material and microorganisms and in understanding of pathogenicity	United States of America
Antiviral peptides discovery	Poland
Awareness-raising communication, confidence-building, and scientific conduct	United States of America
Bioinformatics	Germany, United Kingdom, United States of America
Biological production technologies	United Kingdom
Bioreactors	South Africa
Biosensors	Czech Republic, South Africa
Convergence of biology and chemistry	Australia
Creation of man-made pathogens	China
<u>De novo</u> synthesis of organisms	South Africa
Decontamination	United Kingdom

Diagnostics and epidemiology	South Africa
Disease detection, identification and monitoring technology	Czech Republic
Disease surveillance, sensor and detection technologies	United Kingdom, United States of America
Dispersal technology	South Africa, United Kingdom
Drug delivery systems	Germany, United Kingdom, United States of America
Export control and border security technologies	United States of America
Genetic engineering of viruses	Poland
Genomics laying the foundations for pathogen transformation	China
Genomics, proteomics and other ‘-omics’	United Kingdom
High-throughput whole-genome sequencing	Sweden
Improvements in biosafety and biosecurity practices	United States of America
Industrial application of biotechnology – disposable equipment	United States of America
Medical countermeasures	United Kingdom, United States of America
Microbial forensics	China, Czech Republic, Sweden, United Kingdom, United States of America
Nanotechnology	Czech Republic, Netherlands, South Africa, United Kingdom, United States of America
Neuroscience	South Africa, United Kingdom
Novel therapeutics	Czech Republic
Population-specific genetic markers	China
Simulants and software	Portugal
Specific experiments of concern	South Africa
Strengthening laboratory capacity	Portugal

Synthetic biology	China, Germany, Netherlands, South Africa, United Kingdom
Systems biology	China, South Africa, United Kingdom
Targeted drug-delivery technology making it easier to spread pathogens	China
Vaccine development	Poland, South Africa
Visualization technology	Czech Republic

7. More recently, such science and technology reviews have been supported by contributions from professional scientific organisations and industry (see Chapter 10 for more details). Formal and informal relationships developed by the ISU have helped foster engagement and the flow of information. Prior to the 2006 and 2011 Review Conferences, workshops were convened to identify relevant trends and developments. The 2006 report was distributed to States Parties and introduced in an informal side meeting.⁵ In 2011, the full report was circulated in a similar manner.⁶ In addition, the report's executive summary was included in official documentation of the meeting, as part of a background information document compiled by the Unit.⁷

8. The ISU also now contributes directly to the review. Earlier arrangements only resulted in the compilation of information provided by States Parties. Things began to evolve in 2006, when State Parties requested the Review Conference secretariat to provide a background information document on developments in science and technology. Although the resulting document drew upon contributions by State Parties and information provided by international organisations (including scientific organisations), in format it was a single synthesis summarising individual contributions (which were all still available online). The document covered a broad range of specific advances and developments, an overview of how to identify experiments of dual-use concern, and a list of actual experiments often quoted as being particularly relevant to the Convention.⁸

9. After it began its work in 2007, the ISU started to provide information to State Parties on developments in science and technology. Over the next three years, the Unit produced a series of background document covering specific developments, outreach, as well as oversight information (Table 11.2).

Table 11.2: Biological and Toxin Weapons Convention Implementation Support Unit background information documents on science and technology.

Meeting	Title	Document code
2008 Meeting of Experts	Oversight of Science	BWC/MSP/2008/MX/INF.3
2008 Meeting of States Parties	Background Information on Scientific and Technological Developments that may be Relevant to the Convention	BWC/MSP/2008/INF.1
2009 Meeting of States Parties	Background Information on Scientific and Technological Developments that may be Relevant to the Convention	BWC/MSP/2009/INF.1
2010 Meeting of States Parties	Background information on scientific and technological developments that may be relevant to the Convention: report on an international workshop in Beijing	BWC/MSP/2010/INF.1
Seventh Review Conference	New scientific and technological developments relevant to the Convention	BWC/CONF.VII/INF.3 & Add.1-3, Corr.1-2
	Scientific and Technological Developments that may be Relevant to the Convention	Online only
2012 Meeting of Experts	Advances in enabling technologies	BWC/MSP/2012/MX/INF.1
	Making avian influenza aerosol-transmissible in mammals	BWC/MSP/2012/MX/INF.2

	Science and technology developments that have potential benefits for the Convention	BWC/MSP/2012/MX/INF.3
2013 Meeting of Experts	Advances in science and technology related to the Convention	BWC/MSP/2013/MX/INF.1/Rev.1
2014 Meeting of Experts	Advances in science and technology related to the Convention	BWC/MSP/2014/MX/INF.3 & Corr.1

10. For the Seventh Review Conference, State Parties requested the ISU to prepare another background document. The Unit, when putting together its paper, was now able to draw upon its own in-house expertise and a catalogue of past publications, as well as contributions by international organisations. The ISU paper was prepared prior to contributions from State Parties, and so for the first time complemented, rather than relied on, their efforts. (See Box 11.1 for an overview of relevant background information)

Box 11.1: An overview of the background information document on developments in science and technology for the Seventh Review Conference of the Biological and Toxin Weapons Convention.⁹

General trends:

- Convergence of scientific disciplines;
- Increasing understanding of the life sciences;
- Trends in biotechnology;
- Global distribution in capacity;
- Open science;
- Media, perceptions and society.

Summary of developments with potential negative implications for the Convention:

- Specific research and projects of interest;
- Advances with potential for weapon applications;
- Enhancing or producing a biological weapon agent;
- Circumventing existing control mechanisms;
- Neurobiology.

Review of developments with possible beneficial consequences:

- Detection;
- Diagnostics;
- Prevention and prophylaxis;
- Therapeutics;
- Response capacity.

Overview of enabling technologies:

- Characterising biological systems and networks;
- Manipulating biological systems and networks;
- Engineering biological systems and networks;
- Gathering and manipulating biological information;
- Converting it into digital data and back;
- Generic enabling technologies.

Summary of a workshop held by the international scientific organisations

Individual contributions from State Parties.

11. This short document was supplemented by the ISU with a more comprehensive exploration of the first four sections, made available online.¹⁰

Annual review of developments in the field of science and technology

12. At the Review Conference in 2011, State Parties agreed that five-yearly reviews of developments in science and technology were insufficient to keep pace with progress. They created a Standing Agenda Item on reviewing such developments, as part of their 2012-2015 inter-sessional work programme. Each year State Parties undertook to consider new science and technology developments that: (1) have potential for uses contrary to the Convention; (2) have potential benefits for the Convention; and (3) are relevant to the activities of other relevant international bodies (such as the regime to prohibit chemical weapons). In addition, State Parties would look at measures: (4) for strengthening national biological risk management (including biosafety, biosecurity and identifying and overseeing dual-use research); (5) to encourage responsible conduct by scientists; and (6) for furthering education and awareness raising measures.¹¹

13. In line with the other topics covered by this work programme, this review would be considered at a technical level at a Meeting of Experts (MX) in the middle of the year, and more formally at a MSP towards the end of the year.

14. State Parties also identified a theme for their work each year, covering:

i. In 2012, “advances in enabling technologies, including high-throughput systems for sequencing, synthesizing and analysing DNA; bioinformatics and computational tools; and systems biology”;

ii. In 2013, “advances in technologies for surveillance, detection, diagnosis and mitigation of infectious diseases, and similar occurrences caused by toxins in humans, animals and plants”;

iii. In 2014, “advances in the understanding of pathogenicity, virulence, toxicology, immunology and related issues”; and

iv. In 2015, “advances in production, dispersal and delivery technologies of biological agents and toxins”.¹²

15. In practice, input into these reviews has been limited. Based upon the information available on the Convention’s website, during the first three years of the process two State Parties each presented three working papers or presentations,¹³ two State Parties each contributed two working papers or presentations,¹⁴ and nine other State Parties either made a presentation or submitted a working paper.¹⁵ Although these figures do not take into account impromptu interventions and smaller contributions, it does suggest that there is a limited willingness or capacity to engage in this format of review.

16. To date, the ISU has produced five background documents covering the allocated themes, as well as potential benefits for the Convention (Table 11.2). The background information provided by the Unit for these annual reviews has been the result of the Unit’s own research and interactions with the scientific community.

Role of the Convention’s Implementation Support Unit in reaching out to scientists and technologists

17. Since its inception, the ISU has had a close working relationship with scientists. To the extent practicable, the Unit has also attempted to give back by participating and contributing to scientific endeavours.

18. The reciprocal nature of this relationship is best illustrated by the ISU's interactions with the synthetic biology community. The relationship began in 2006 at the workshop held by the international scientific organisations prior to that year's Review Conference. This workshop included an overview of synthetic biology. The ability to engineer biology effectively would clearly have significant implications for the Convention - both positive and negative. The Unit remained in contact with synthetic biologists present at that meeting and, as a result, in 2008 was invited to present on the Convention in a plenary session of SB4.0 in Hong Kong. This was the fourth in a series of global scientific congresses on synthetic biology. The Unit was invited back to SB5.0 at Stanford University in 2011 to participate in a panel on interacting with society, and for a talk at SB6.0 in London in 2013. At this last meeting, an initiative by the Unit in coordination with the Organisation for the Prohibition of Chemical Weapons and with the support of the World Health Organization, held an awareness-raising side event.

19. ISU contributions to scientific meetings on synthetic biology were not limited to big international events. The Unit also participated in national meetings on the topic from Pakistan to the US, and from Jordan to France. Each event provided a unique opportunity to: (1) raise awareness of the Convention and the potential for science to be misused by others to cause deliberate harm; (2) highlight how engagement with the topic could be integrated into broader efforts on responsible conduct; (3) help advance scientific careers; and (4) open doors to the best science. It also provided an opportunity to illustrate how scientists can contribute to, and influence, international policy processes that impact their work.

20. The ISU has also been able to work with the synthetic biology community on practical efforts to help prevent the deliberate misuse of synthetic biology. For example, from 2009-2014, the Unit worked closely with the International Genetically Engineered Machines Competition (iGEM), the foremost international synthetic biology competition. A member of the Unit has contributed to Federal Bureau of Investigation

outreach events (see Chapter 12 for more details), helping to raise awareness amongst this community of the need to actively engage in safeguarding good science. A member of the Unit has also been a judge in the iGEM competition, initially in human practices, and then later as a committee member of the newly created Policy and Practices track. The ISU member was also the original coordinator for security issues, and later a founder member of the Safety Committee of the competition, which continues to ensure that all the teams are working safely and securely.

21. Building upon these relationships and to showcase what they had learnt, from 2008-2010 the ISU hosted a series of briefing on the margins of formal Convention meetings. In 2008, the Unit, jointly with the Geneva Forum, hosted an introduction to synthetic biology for policy makers. This event included a briefing on options for the governance of synthetic genomics. The following year, at the MSP the Unit highlighted the potential importance of synthetic biology, by showing a series of short videos, including on potential benefits for health, industrial production, as well as art and culture. The Unit held two events in 2010. At the MX, the first looked at how synthetic biologists were engaging in discussions on the implications for society, with a particular focus on safety. The second event, on the margins of the last meeting prior to the 2011 Review Conference, addressed security.

22. The ISU has helped to facilitate synthetic biologists and scientists more broadly, to contribute to the work of the Convention. The Unit has helped ensure that synthetic biologists were present amongst guests invited to technical meetings. The Unit also liaised closely with relevant scientists and helped them organise their own events on the margins of Convention meetings: for example, sessions on developments in science and technology, dealing with dual-use technology, and strengthening the web of prevention, have accompanied every meeting in the current intersessional process.

23. The ISU has made use of its relationships with scientists to facilitate their involvement in other international disarmament and non-proliferation processes. For example, the Unit participated as a member of the Temporary Working Group on the Convergence of Biology and Chemistry, of the Scientific Advisory Board of the Organisation for the Prohibition of Chemical Weapons (see Chapter 9). The Unit contributed to briefing of the Temporary Working Group on the ISP. Drawing upon its

relationship with synthetic biologists and the citizen science (DIYBio) movement, the Unit enabled a wide range of scientists to brief the Temporary Working Group. The Unit also provided to the Temporary Working Group briefings on relevant scientific and technical developments which it had identified through its work with scientists.

Opportunities for scientists to contribute to the Biological and Toxin Weapons Convention

24. Scientists already contribute a great deal to the work of the Convention. Perhaps the most traditional role they play (from a policy perspective) is as technical experts on behalf of individual countries. A few State Parties employ technical experts to focus solely on issues related to biological weapons. Many more draw upon the expertise of their national scientific community as necessary. Certainly, as work becomes more technical, policy experts need to talk to scientists to understand the implications of developments in science, and how best to maximise their benefits, whilst minimising risks. Scientists are also regularly members of the national delegations to the Convention's meetings in Geneva.

25. Delegations have also helped national scientists contribute to the work of the Convention. For example, in 2014 Canada supported the efforts of the iGEM team from Calgary.¹⁶ The team attended the MX, made a statement to an informal session,¹⁷ presented a poster, and was recognised in an official national contribution in the formal sessions dealing with developments in science and technology.

26. More recently, individual scientists with specific expertise have been invited by the annual Chairs to participate in the work of the MX as Guests of the Meeting (Box 11.2). Guests of the Meeting make a presentation to the formal meetings, can submit additional written resources, and are free to question or add to the contributions of others. The ISU plays an important role in identifying potential guests. Whilst Review Conferences have, traditionally, not invited guests, in 2011 Professor Indira Nath from India was asked by the President of the Seventh Review Conference to give a keynote

opening address. Her message was followed by a contribution by Ester Ng from Singapore, the winner of an international essay contest for young scientists on responsible conduct (Box 11.3).

Box 11.2: Countries of Origin of Guests of the Meeting since 2008.

Brazil
Canada
China
Germany
India
Jordan
Philippines
Poland
Republic of Korea
Singapore
Switzerland
United Kingdom
United States of America

Box 11.3: An international young scientist essay contest.¹⁸

In the run up to the Seventh Review Conference, the ISU in collaboration with the Governments of the Netherlands, Switzerland and the United Kingdom, ran an essay contest for graduate and undergraduate science students on responsible conduct in the life sciences, and the importance of safety and security, as well as the role for international collaboration.

Over forty entries from around the world successfully passed through the initial selection. Ten were short-listed, including entries from Africa, the Americas, Asia-Pacific, Europe and Central and Southern Asia. Five were selected as finalists by members of the ISU, and the winner was chosen by the President-designate of the Review Conference.

The winning essay was written by Ms. Esther Ng from Singapore, who was studying Genomic Medicine and Statistics at Oxford University in the UK. Her essay

“Biosecurity – The role of young scientists” won her a glass microbe sculpture from the renowned artist Luke Jerram, and an all expenses paid trip to Geneva to read her essay to the Review Conference.

27. Scientific bodies can also participate in their own right as non-governmental organisations. They can then observe public parts of the meetings (which have comprised virtually all of the 2003-2005, 2007-2010 and, so far, the 2012-2015 ISPs) and an informal session is traditionally set aside to hear their statements. Documents, background information and other resources produced by these scientific organisations are brought to the attention of official delegations by the ISU, through the Convention’s website.¹⁹

28. Since 2008, MX meetings have included poster sessions, open to all participants, including scientific organisations. Whilst commonplace at scientific and technical meetings, poster sessions are not a standard feature of international policy processes. There are also a limited number of rooms made available over breakfast and lunchtimes during formal meetings, for side events and briefings. Many of these events are organised by, or include, scientists. Science bodies, such as the US National Academy of Sciences, have also held pre-meetings to the formal schedule, and retreats which target technical experts and policy makers.

29. Finally, the ISU has also hosted post-graduate interns. These individuals provide much needed support to the work of the Unit, but they also experience first-hand what such a Unit does. Whilst many of the past interns have a background in disarmament or science policy, in a few cases scientists have joined the Unit. They have been well placed to draw upon their scientific knowledge and help to build bridges between science and security.

Evolution of the Biological and Toxin Weapons Convention Implementation Support Unit

30. Institutional support for the Convention has changed considerably since it entered into force. It continues to evolve. In its early days, the Convention was serviced by the United Nations, and administrative support for meetings was provided directly by the

UN Office for Disarmament Affairs. Convention funds were used to bring their staff to meetings.

31. The Convention got its own dedicated staff in the 1990s. The Chairman of the Ad Hoc Group (AHG), Ambassador Tibor Toth of Hungary (see Chapter 6), requested and received a dedicated assistant; by the end of the AHG, a second, part-time position had been added. Both posts were to provide substantive support to the Chairman in his efforts to oversee negotiations towards a legally-binding Protocol to the Convention.

32. To help with preparations for the Fifth Review Conference, an additional staff member was recruited to oversee Convention issues inside the United Nations. This new staff member was to become the Secretary of the Fifth Review Conference. Two additional unpaid assistants were also added to the team.

33. The Fifth Review Conference, despite being suspended for a year, eventually agreed to an ISP in the lead up to the next Review Conference. To support State Parties in this endeavour, the United Nations was allocated funds by State Parties to recruit a small secretariat to service the meetings. This Unit researched and published background documents, and provided substantive and administrative support to the annual Chair in addressing the allocated element of strengthening Convention implementation. The team comprised three and a half posts.

34. In the lead up to the Sixth Review Conference, a broad range of State Parties began to table proposals for dedicated institutional support for the Convention. The idea gathered momentum and ultimately resulted in the ISU. In his reflections on the Sixth Review Conference, its President, Ambassador Masood Khan of Pakistan, described establishing the Unit as ‘historical’, noting:

For many years, the States Parties have debated the need for institutional support for the Convention. Now we have it, built not on a political argument, nor on a perception that “something is better than nothing”, but on the solid basis of the positive and practical contribution the temporary secretariat has made over the past three years.²⁰

35. The ISU was created as a three-person Unit to be housed in the Geneva Branch of the United Nations Office for Disarmament Affairs. It had (and has) a “sunset clause” built in – it would cease to exist at the next Review Conference if State Parties took no action. The Unit’s original mandate included providing (1) administrative support, such as preparing documents, facilitating communications (including with scientific organisations), a focal point for information exchanges, and supporting implementation decisions taken by State Parties; (2) facilitating annual exchanges of information, such as reminding State Parties to participate and facilitating that participation, as well as receiving, compiling and distributing data, and developing an online platform to do that.²¹ Additional tasks were added to the mandate at the Seventh Review Conference: to establish and administer a database for assistance requests and offers; and to support the implementation of other decisions and recommendations of the Seventh Review Conference.²²

Looking forwards

36. The ISU is likely to continue to evolve. The next Review Conference will review the Unit’s functioning once again. No matter the outcome, some support structure will be required, and the ISU has demonstrated that it can do the job.

37. The next Review Conference may well establish a more centralised process for reviewing scientific progress. There is certainly political support for an effective review process. In the lead up to the Seventh Review Conference, a working paper by India asserted that the “need for structured and systematic review of scientific and technological developments relevant to the Convention has been identified by a large number of member states as an important issue.”²³ Such views led to the standing agenda item in the 2012-2015 ISP.

38. There are signs that some countries think there is a need to improve these arrangements. For example, in December 2013 Switzerland tabled a working paper noting that “experiences over the last two years have shown the limitations of the current process.”²⁴

39. A number of countries have determined what such a review might accomplish. For example, a 2011 working paper by Australia, Japan and New Zealand detailed a multi-stage process to: (1) identify relevant developments - a task it was suggested best suited to international scientific bodies; (2) consider their implications for the Convention, which could be undertaken by national technical experts as part of the work of the MX; (3) any necessary follow up or action required would then be decided by the MSP.²⁵ Whilst there seemed to be broad agreement over the importance of these three steps, there was less consensus as to who should undertake the work, or what structure might be most appropriate.

40. The same group of State Parties proposed establishing a Science and Technology Working Group, which would provide continuity throughout an ISP; provide a vehicle for structured reviews; and in particular identify potential implications through interactions between scientists and policy makers, as well as providing a firm foundation for the five yearly review of science and technology at Review Conference. Such a working group, it was suggested, would also provide a useful vehicle for education – both helping to promote understanding of the objectives of the Convention amongst scientists, and also familiarising diplomats and policy makers with relevant science and technology.

41. There have been more recent calls to explore alternatives. The Swiss working paper for the 2013 MSP suggested that a working group, comprised of experts nominated by State Parties and open to the participation of all States Parties, might be a suitable model. Switzerland has indicated its willingness to convene a process to “exchange views and, if feasible and appropriate, to elaborate a joint concept paper to be submitted to the Eighth Review Conference in 2016, with the aim of having a stronger BWC capable of adequately addressing relevant developments in science and technology.”²⁶

Conclusion

42. How the Convention reviews relevant science and technology may well change in the coming years. Different models for conducting reviews each come with particular

strengths and weaknesses: past experience suggests that models confined to contributions from State Parties can result in a relatively small group of contributors; conducting entirely external reviews expands opportunities to provide input, but exacerbates challenges in identifying implications; and making use of a body with feet in both camps, such as an ISU, carries distinct resource implications and a need for legitimacy with both communities. Shaping how the process develops, and how this Convention is exposed to, and thinks about, developments in science and technology, should be of concern to scientists. Contributing to this process, and ensuring that this Convention is well equipped to make science-based policy, is a challenge that will undoubtedly remain throughout the reader's career.

References

¹ For more information on the roles and responsibilities of secretariats in multilateral conventions, see for example: Secretary-General's High-level Panel on UN System-wide Coherence in the Areas of Development, Humanitarian Assistance, and the Environment, *Basic Information on Secretariats of Multilateral Environmental Agreements: Mission, Structure, Financing and Governance*, United Nations, <http://www.un.org/ga/president/61/follow-up/environment/060612d.pdf> (Accessed 8 June 2015).

² See for example the arrangements for the 2016 review conference decided by the 2011 review conference: Biological Weapons Convention, *Final Document of the Seventh Review Conference*, BWC/CONF.VII/7, paragraph 66. This and other official documents of the BWC can be found on their website at www.unog.ch/bwc/docs.

³ See for example, Biological Weapons Convention, *Provisional Agenda*, BWC/CONF.VII/1.

⁴ Implementation Support Unit, *New scientific and technological developments relevant to the Convention*, BWC/CONF.VII/INF.3/Add.1-3.

⁵ Royal Society, *Report of the RS-IAP-ICSU international workshop on science and technology developments relevant to the Biological and Toxin Weapons Convention*, RS policy document 38(06), November 2006, https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2006/8245.pdf (accessed 30 June 2015).

⁶ National Research Council, *Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention: Summary of an International Workshop: October 31 to November 3, 2010, Beijing, China*, National Academies Press, 2011, <http://www.nap.edu/catalog/13113/trends-in-science-and-technology-relevant-to-the-biological-and-toxin-weapons-convention> (accessed 30 June 2015).

⁷ Implementation Support Unit, *New scientific and technological developments relevant to the Convention*, BWC/CONF.VII/INF.3, This document is the most recent, comprehensive

overview of developments in science and technology relevant to the Biological Weapons Convention.

⁸ Implementation Support Unit, *Background Information Document on New Scientific and Technological Developments relevant to the Convention*, BWC/CONF.VI/INF.4.

⁹ Biological Weapons Convention, *New scientific and technological developments relevant to the Convention*, BWC/CONF.VII/INF.3/Add.1-3.

¹⁰ Implementation Support Unit, *Scientific and Technological Developments that may be Relevant to the Convention*,

[http://unog.ch/80256EDD006B8954/\(httpAssets\)/60DF13D6F1C36120C1257935003301CB/\\$file/Scientific+and+Technological+Developments+that+may+be+Relevant+to+the+Convention++no+refs.pdf](http://unog.ch/80256EDD006B8954/(httpAssets)/60DF13D6F1C36120C1257935003301CB/$file/Scientific+and+Technological+Developments+that+may+be+Relevant+to+the+Convention++no+refs.pdf) (accessed 17 March 2015).

¹¹ Biological Weapons Convention, *Final Document of the Seventh Review Conference*, BWC/CONF.VII/7, Decisions and Recommendations, paragraph 22. This document established the current work programme of the Convention, describes how it reviews developments in science and technology, and sets the parameters of the next major international review conference.

¹² Ibid, paragraph 23.

¹³ United Kingdom and United States of America.

¹⁴ Germany and Sweden.

¹⁵ Australia, China, France, Japan, Mexico, Poland, Russian Federation, Spain, and South Africa.

¹⁶ 2014 Calgary iGEM team, *Biological & Toxin Weapons Convention*,

<http://2014.igem.org/Team:Calgary/PoliciesAndPractices/BiologicalWeaponsConvention> (accessed 17 March 2015).

¹⁷ A video of their statement is available at https://www.youtube.com/watch?v=_zexaTv8pqq (accessed 17 March 2015).

¹⁸ Implementation Support Unit, *Essay Contest*,

[http://www.unog.ch/unog/website/disarmament.nsf/\(httpPages\)/3F84B2DD92681BF6C1257AC200513D5A?OpenDocument&unid=F1CD974A1FDE4794C125731A0037D96D](http://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/3F84B2DD92681BF6C1257AC200513D5A?OpenDocument&unid=F1CD974A1FDE4794C125731A0037D96D) (accessed 17 March 2015).

¹⁹ Implementation Support Unit, *Contributions from Scientists*,

[http://www.unog.ch/80256EE600585943/\(httpPages\)/8B99A8941E082DFCC1257AC50033DCA3?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/8B99A8941E082DFCC1257AC50033DCA3?OpenDocument) (accessed 17 March 2015). This list of documents compiles a large number of resources produced by scientific organisations pertinent to the Biological Weapons Convention.

²⁰ Ambassador Masood Khan, *Closing Remarks*,

[http://unog.ch/__80256ee600585943.nsf/\(httpPages\)/3496ca1347fbf664c125718600364331?OpenDocument&ExpandSection=1#_Section1](http://unog.ch/__80256ee600585943.nsf/(httpPages)/3496ca1347fbf664c125718600364331?OpenDocument&ExpandSection=1#_Section1) (accessed 17 March 2015).

²¹ Biological Weapons Convention, *Final Document of the Sixth Review Conference*, BWC/CONF.VI/6, Decisions and Recommendations, paragraph 5.

²² Biological Weapons Convention, *Final Document of the Seventh Review Conference*, BWC/CONF.VII/7, Decisions and Recommendations, paragraph 32.

²³ India, *Proposal for structured and systematic review of science and technology developments under the Convention*, BWC/CONF.VII/WP.3.

²⁴ Switzerland, *Establishing a dedicated structure for the review of developments in biological science and technology*, BWC/MSP/2013/WP.5. This document includes an assessment of the current process to review developments in science and technology and includes a call for an improved process to be agreed at the next review conference.

²⁵ Australia et al., *Proposal for the annual review of advances in science and technology relevant to the Biological Weapons Convention*, BWC/CONF.VII/WP.13.

²⁶ Op cit, note 24.

Chapter 12: The Federal Bureau of Investigation Biosecurity Program: Case study of law enforcement engagement and outreach

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Key learning objectives

- i. Security of biological material, technology, and expertise requires national government resources and life science enterprise buy-in for effective implementation of prevention measures.
- ii. National law enforcement agencies have roles and responsibilities to safeguard research and biotechnology development. The primary function of safeguards is to prevent illicit acquisition by nefarious actors and groups with extreme ideological agendas. Those same safeguards have secondary benefits – they support the growth of national economies.
- iii. Development of legislation and regulations needs to include all affected stakeholders.
- iv. Partnerships developed through trust and understanding, and establishing robust communications between the security and research sectors, are essential, and will support the evolution of prevention mechanisms that keep pace with the speed and direction of research and biotechnology development.

Introduction

1. The biological and medical research arena is rapidly evolving, as is evident from the pace of life science discoveries and biotechnology development. A culture of openness, collaboration, and sharing of ideas, materials, and knowledge supports the advancements. The ease of communications and exchange of ideas and data in the ‘Internet of Things’ certainly contributes to the latest pace of advances. However, scientists, staff, and institutions that conduct the

research are threatened and can be exploited by nefarious actors for their possessions, expertise, and proprietary information, either for extreme ideological reasons or economic gains. These threats may be physical, meaning intrusions by outsiders or insiders, or they can be cyber-related. The United States Government's (USG) departments and agencies have instituted a variety of programs to safeguard the life science enterprise from these threats.

2. The Federal Bureau of Investigation (FBI) in the United States (US) is the lead Federal law enforcement agency charged with preventing, detecting, deterring, and investigating acts of terrorism using chemical, biological, radiological, nuclear, and explosive (CBRNE) materials. This chapter showcases the approach and resources that FBI has dedicated in its prevention mission; the perceived and real challenges; how the Weapons of Mass Destruction (WMD) Directorate's Biosecurity Program within the FBI complements other USG initiatives and regulatory frameworks; and lessons learned to prevent illicit acquisition and use of biological material, technology, and expertise.

3. The FBI is a national-level law enforcement agency working with regulatory agencies, but is not a regulatory agency in itself. As such, the FBI has a different perspective on biosecurity – purely from the security point of view and engages the scientific enterprise differently. Working at and with the research sector at the national, regional, and local levels, the FBI supports the development of feasible and implementable prevention mechanisms to reduce biosecurity vulnerabilities. The WMD Directorate's workforce is made up of scientists, analysts, and law enforcement officers, working side by side. This unique composition in a law enforcement agency enables the FBI to overcome perceived and real challenges that evolve with the rapid pace of research and biotechnology development. The subject matter experience has created a successful Biosecurity Program for domestic institutions, and the engagement model is requested by international partners. Another unique feature of the FBI is the Weapons of Mass Destruction Coordinator, a local point-of-contact who serves as a conduit to locally available resources and national reach-back capabilities, and brings experience and subject matter understanding at the local level. The WMD Coordinator programme essentially means that it is possible for all institutions of the life science enterprise in the US to be in contact with and obtain FBI support

and resources, to ensure security of biological material, technology, and expertise, and the safety of those involved in research.

Federal Bureau of Investigation Weapons of Mass Destruction Directorate

4. The FBI's Weapons of Mass Destruction Directorate (WMDD) (Figure 12.1) was established



Figure 12.1: FBI WMD Directorate Seal

in July 2006, with the mission of preventing, detecting, deterring, and investigating crimes using chemical, biological, radiological, nuclear, and explosive (CBRNE) materials within the US, and against US interests abroad. A cadre of personnel with analytical, investigative, and subject matter experience in CBRNE, which existed within the

FBI since the 1990s, was consolidated into the new division. Three sections of the WMD Directorate: Countermeasures Operations; Intelligence Analysis; Investigations and Operations, work hand-in-hand to achieve the mission. The Countermeasures Operations Section consists of four units: each develops countermeasures and tripwires to prevent illicit acquisition or misuse specific to their modality: Chemical Countermeasures Unit, Radiological and Nuclear Countermeasures Unit, Biological Countermeasures Unit, and Infrastructure Countermeasures Unit.

5. The WMD Directorate is also the coordination body for the WMD Coordinators. The WMD Coordinator (Table 12.1) is unique among national-level law enforcement agencies globally. FBI Special Agents must complete a curriculum of course work and have investigative and response experience before being certified as WMD Coordinators. And, once certified, they must obtain continual education credits to stay appraised of CRBRNE developments. Each of the FBI's 56 Field Offices throughout the US has a WMD Program with at least one WMD Coordinator. They serve as the FBI's local points of contact in all WMD related matters, working with local, State, and regional Federal agencies, such as public health, emergency services, and other law enforcement entities. Two US Embassies currently have WMD Assistant Legal Attaches (ALAT), one in Tbilisi, Georgia and the other in Singapore. The WMD ALATs support international partners in those regions on all WMD matters. A third WMD ALAT is due to be stationed in the Middle East.

6. The Biological Countermeasures Unit (BCU) leads the FBI's efforts to develop mechanisms to prevent, detect, and deter crimes using biological material. The personnel also provide subject matter advice during investigations of potential misuse of biological material. The prevention efforts require the BCU to engage with the life science community – research, industrial, and biotechnology sectors.

Development of Regulations, Policies, and Guidance

7. The development of laws, regulations, and policies by national governments is often in response to an event of significance, an event which demonstrates that existing mechanisms are inadequate and unable to minimize the risks or vulnerabilities.

8. The first such event was in 1995 when Larry Wayne Harris, a former microbiologist, purchased Yersinia pestis, the causative agent of plague, from a culture collection organization. Harris was also a high ranking member of a white supremacist group, and held anti-government views. Harris became the focus of a law enforcement investigation when he misrepresented the purpose of the purchase to the seller. He was arrested and charged on two counts of mail fraud and one count of wire fraud.¹ While on probation, an informant told authorities that Harris was plotting a

Table 12.1: FBI WMD Coordinator Program

FBI WMD Coordinators

Primary Points of Contact
at the local level

1. At least one WMD Coordinator in each of the FBI's 56 Field Offices
2. Contacted by state and local Emergency Responders when confronted by a WMD threat or incident
3. Liaison with Federal regional counterparts and state and local response agencies
4. Liaison with entities in their jurisdiction (industry, academia)
5. Act as a conduit to FBIHQ and the Federal Government for technical information, advice, and assistance

bioterrorism scheme. He was again arrested in 1998 and this time charged with Title 18 United States Code 175, the development and stockpiling of a biological weapon.²

9. The United States Federal Select Agent Regulations (SAR) was developed (April 1997) as a result of Harris' actions. This is an example of governmental action because of a revealed vulnerability – no system in place to track the transfers of biological agents and toxins that could have severe health consequences to human, animal, or plant. The SAR established an oversight mechanism for a list of pathogens and toxins that have been determined to have severe impact on human, animal, and plant health and the economy, if released accidentally or intentionally. This list is also known as the Biological Select Agents and Toxins (BSATs). Two agencies have regulatory oversight of the United States Federal Select Agent Program: the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), has oversight authority over pathogens and toxins that affect human health; the Agriculture Select Agent Services (AgSAS), within the United States Department of Agriculture (USDA), has oversight authority over pathogens and toxins affecting animal and plant health. There are also import/export controls on pathogens of concern under the purview of the Department of Commerce.

10. The second event which significantly altered regulations and policy regarding biological agents of concern was the anthrax mailings in October of 2001. It profoundly changed the threat perspective in the US, but also globally. The 2003 SAR revisions required any facility or individual that possesses, uses, or transfers any one of the BSATs to be registered with the Federal Select Agent Program. As part of the registration process, the FBI conducts a criminal background database check, known as the Security Risk Assessment (SRA), which is taken into account by HHS or USDA prior to the facility or individual being granted access.

11. The US regulatory oversight on BSATs in response to Larry Wayne Harris and the anthrax mailings was viewed as an overreaction by much of the research community. The scientific community believed there would be significant cost and impact on research due to these changes.³ Discussions continue to date on balancing between privacy rights, freedom to conduct basic and applied research, and mechanisms to strengthen and protect national security.⁴

12. When the SAR were due for biannual review in 2010, a wholly different and more transparent process was undertaken. The USG took a more systematic approach to determine which pathogens and toxins should be considered as BSATs (Table 12.2). The research community was involved early on, and selected members were part of the revision process. Researchers and subject matter experts were invited to speak in front of various working groups, and their comments and input were considered during the deliberation process. As with other proposed regulatory changes or public policies, a period for public comment was provided to gain additional insight and input.⁵

Table 12.2: Informed Policy Decision-Making

Informed decisions for the development of regulations and policies can be reached only when those affected, e.g. the scientific community, are involved and provide support to their governmental counterparts.

Federal Bureau of Investigation's Biosecurity Program

13. Today, the scientific community has a better perception of, and is in partnership with, the FBI to strengthen biosecurity measures. However, this has not always been the case. The perception and acceptance of the FBI by the scientific community was perhaps at the lowest point when the WMD Directorate was stood up. The negative perception was based on several events, and a new set of regulations was considered as a barrier, stymieing scientists' ability to conduct research.

14. The FBI was in charge of the investigation to determine who sent anthrax spores through the United States Postal System. The investigation, known as Amerithrax⁶, focused on individuals inside and outside the United States who had access to the Bacillus bacteria. Many within the scientific community did not believe, and some still do not, that one of their own members could have possibly committed this act, which resulted in five fatalities, shutting down several facilities, thousands placed on antibiotics, and over a billion US dollars in cleanup cost. The sentiment against the FBI increased during the early part of the Amerithrax investigation, when

one of the main subjects was cleared, but only after much media attention centered upon him and was said to have negatively affected his professional standing.⁷ The attitude towards the FBI was further degraded, when scientists who had long worked with BSATs were required to undergo the SRA and be registered in the Federal Select Agent Program.

15. A study⁸ (Table 12.3) which assessed the willingness of academics and scientists to talk to and collaborate with law enforcement showed:

- a. Members of the scientific community responded similarly to members of the general public when asked about how they felt about the FBI;
- b. There was a significant drop in the willingness of scientists to speak with law enforcement representatives, compared to other science colleagues, general public, and even the media; and
- c. Only a very small percentage believes that law enforcement should have a role in monitoring scientific research.

The study report had recommendations as to how law enforcement can improve its relationship with the science community. These include: 1. Stating their goals and motives at the start, 2. Improving science literacy, and 3. Be less adversarial and more respectful.

Table 12.3: How Scientists View Law

“many in the scientific community hold a negative view of law enforcement...this divide is a serious liability to law enforcement, since cooperation and consultation with scientists aids in threat assessment, investigation, intelligence gathering, and the recruitment of personnel with specialized skills.”

16. A significant challenge had to be overcome. The Biological Countermeasures Unit took these results and recommendations, and made significant changes to its outreach and Biosecurity Program. One of the first steps was to recruit talented individuals with science backgrounds. In other words, the FBI hired more individuals who can ‘talk the talk’ – understand the technical aspects when speaking with researchers and technologists. The second step was to change scientists’ perceptions by ensuring that the right message was conveyed, including that both communities benefit through collaboration. And lastly, prevention mechanisms were developed in conjunction with the practitioners of science, with the focus on safeguarding the sciences (Figure 12.2 and Table 12.4).

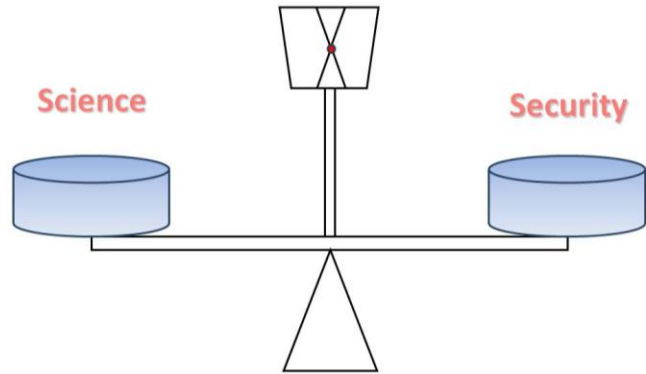


Figure 12.2: Striking a Balance Between Science and Security

Table 12.4: Core Tenets of FBI Biosecurity

<u>Core Tenets of Biosecurity Engagements</u>	
1	Different missions that are both vitally important and contribute to national security.
2	Partnerships built only through mutual understanding and trust.
3	Feasible, effective biosecurity measures implemented without hindering scientific progress and innovation.
4	Different set of experiences and expertise to develop measures minimizing potential nefarious acts, evolving with the threat spectrum, with advancements in scientific knowledge and innovations.

17. The scientific background of BCU personnel means they appreciate the need for scientific research and that unnecessary, overly burdensome requirements could hinder science advancements. They also recognize that basic and applied research support and improve national security, by developing rapid and early medical diagnostics, countermeasures, and therapeutics and innovating biotechnologies. Scientific members are pleasantly surprised when the FBI representatives they engage with understand their needs, appreciate their work, and matriculated graduate degrees in the life sciences (MS and/or Ph.D.).

18. Another benefit of having scientists working in a law enforcement agency with a security mission, such as the FBI, is the ability to see the world from the other lens. There are individuals and groups that want to perpetrate heinous acts because of extreme ideology. Many scientists are reassured and removed from these threats because governments are poised to prevent and disrupt those acts. As such, their perception and realization of threats is different from that of those who are responsible for a nation's protection and security. The advantage is that they can place other focus and effort on other societal priorities, such as scientific research. The BCU Biosecurity Program raises threat awareness among the scientific community in order to increase protection of researchers and the research (Table 12.5).

Table 12.5: Starting Biosecurity Engagements

Multiple Levels of Biosecurity Engagement

Law enforcement and security agencies can start biosecurity conversations by engaging national level scientific organizations at their annual members meetings. The biosecurity message can be broadcasted widely and individual members can take the information back to their respective home institutions, where follow on conversations can be had.

Examples of national-level scientific organizations include:

1. National science academies
2. National/regional biosafety associations
3. National peer-reviewed science journals
4. National/regional university associations
5. National/regional science associations

19. The unique combination of the FBI's personnel and the scientific community enables the establishment of understanding in respective roles and responsibilities. The trust built from this meaningful dialogue, and from recognition that each community has its own valuable experience and expertise, often results in development of effective and implementable biosecurity mechanisms.

Scope of the FBI Biosecurity Program

Security of 'Agents of Concern' and beyond

20. The CDC and USDA have regulatory oversight on 65 pathogens and toxins, currently. Those 65 agents are considered to have significant impact on human, animal, plant health and the economy if accidentally or intentionally released. As such, institutions are required not only to register if they possess, use or transfer these agents, but also to report any theft, loss, or release to the Federal Select Agent Program and the FBI. These same institutions are under a greater threat as targets by nefarious actors, because of their biological material and expertise. One of BCU's outreach focuses is to those registered facilities. However, there are a few factors as to why the FBI Biosecurity Program is not narrowly concerned with biological agents on the Select Agent list. The first of these factors is that the potential to cause intentional harm can involve agents outside that list. Second, the list of BSATs is reviewed every two years, in order to capture novel and emergent pathogens which may have been identified during that lag time and would be outside of regulatory control. Finally, advances in biology may have unforeseen vulnerabilities, which the science and security communities need to address collaboratively.

The people of the scientific enterprise

21. Personnel suitability/reliability programmes (PRP) are required in the US, based on the October 2012 revisions of the SAR. However, this requirement pertains only to a subset of registrants – facilities and those who have access to Tier 1 BSATs⁹ – pathogens that have been determined to have the highest risk to human, animal, and plant health and the economy, if accidentally or intentionally released.

22. There is a debate over the efficacy of PRPs, including among practitioners within the life sciences enterprise – with proponents for and against the need of such programmes. The acceptance of PRPs is difficult.¹⁰ There are two areas of concern. The first area is the need for information, that some believe further impinges on privacy rights – credit history and medical information, that are not technical or competency issues related to laboratory research. The second area is - because it is not well formulated, and is argued as not having empirical data to support – the psychological make-up of a person as a predictor that he/she will commit an act that will harm him-/her-self and/or others. This latter factor requires the hiring institution to gather psychological data, understand and analyse the data, and then be able to draw a conclusion as whether the person has the potential to commit a deliberate act harming him-/her-self and/or others during their career in scientific research and development. Research institutions may not have the in-house expertise or resources to conduct these psychological evaluations.

23. The CDC published related guidance¹¹, with input from other US Federal Departments and Agencies, for the pre-employment screening process. The recommended components are based on human resource departments' best-practices, lessons-learned in the security sector, and the determination of technical competencies necessary to conduct research safely. It is important to note that these recommendations and factors to consider do not constitute a formal psychological or psychiatric evaluation: only a trained and qualified professional can perform such an evaluation.

24. Pre-employment suitability is one of two components of the whole PRP programme. The second aspect is continuous reliability. There are many stress factors throughout a person's career that may affect their world views and perspective on the value of life. These stress factors can be personal or job-related. The continuous reliability component therefore is a mechanism which attempts to detect aberrant changes in the job performance and behavior of individuals. It can be simple – noting and being aware of employees' and colleagues' demeanors, changes in mood or behavior that could affect the safe and secure operations of the institution. Other factors to consider as part of continuous suitability could include random drug testing, periodic financial disclosure and criminal history checks, anonymous self- and peer-reporting of aberrant behavior,

reporting of foreign travel and foreign contact, authorization to access medical records, etc. The most important aspect is that a mechanism exists to support and alleviate the stress factor(s), regardless of the sophistication of the continuous reliability component.

25. Two significant incidents argue for the need for PRPs.

The 2001 anthrax mailings in the US is one of these incidents. As mentioned previously, it resulted in profound changes. It was determined that Bruce Ivins, who worked at the United States Army Medical Research Institute of Infectious Diseases, committed this act of bioterrorism. Ivins committed suicide just prior to his indictment and arrest by the FBI. He was conducting research on Bacillus anthracis for the development of an anthrax vaccine. The Amerithrax investigation revealed he had a history of criminal acts, including breaking and entering and larceny. Ivins was undergoing group therapy sessions that were undisclosed to his employer. Colleagues of Ivins observed and reported concerning behavior; some of these reportings were years prior to the anthrax mailings.

The deliberate crashing of Germanwings Flight 4U 9525 by co-pilot Andreas Lubitz is the second significant incident. Investigations since the crash on March 24, 2015, killing all 150 persons on board, indicate that Lubitz suffered from severe depression, even during pilot training in 2009, and was treated for suicidal tendencies.

The ultimate reason(s) for committing these acts will never be known. However, and in hindsight, strong PRP measures may have prevented the loss of lives. Lessons-learned from other cases studies demonstrate that the PRP should be in place not only in life science research, but also in public health, and other sectors (Table 12.6).

Table 12.6: Pre-employment Suitability and Reliability Programs

Lessons-learned Case Studies of Personnel Reliability Programs

- 1 Verification of education and employment history and credentials – could have saved more than 10,000 USD and months of research.
- 2 System of reporting and follow through - could have saved months of research
- 3 Sector/community commitment – could have prevented a substance abuser from infecting more than 40 people with Hepatitis C
- 4 Sector/community action – could have prevented 13 deaths and 29 injuries

Additional case studies can be found at,
<http://www.aaas.org/sites/default/files/reports/AAAS-APLU-AAU-FBI%20report%20on%20personnel%20security%20070114.pdf>

Advances in Biotechnology

26. Advances in biotechnology development present many case-studies where developers, policy-makers, and the law enforcement-security sector have worked hand-in-hand to protect the health and safety of individuals and the society at large. Taking the evolution of the automobile as an example, one can see many intersections where developers, policy-makers, and law enforcement-security sectors work together – safety improvements developed by the automotive industry, as well as regulation-driven safety requirements in the past century of the automobile; development of traffic and safety laws; and international accords requiring improved air quality control standards of today’s automobile for the good of global society and protection of the environment.¹² Like the example of the automobile, the regulations, safety standards, and security requirements are of paramount importance that evolve with advances in the sciences and biotechnology ensuring the safety and security of individuals, society, and the environment.

27. An example of the sectors working together in the sciences is the growth of the synthetic DNA industry – one report estimated that the global synthetic biology market will grow to over \$38 billion USD by 2020.¹³ Here, a loose comparison is made between the growth of the synthetic DNA and the automotive industries – little or no standards for security at the beginning of either sector. A synthetic DNA security vulnerability was pointed out when a scientific reporter in the United Kingdom purchased a short DNA sequence belonging to the Variola major virus, causative agent of smallpox.^{14,15} The World Health Organization declared smallpox eradicated in May 1980, and vaccination programmes against smallpox ceased soon after. This means that the majority of today’s global population is immunologically naïve. There are only two research laboratories that retain the smallpox virus for the purpose of conducting protective research. One of these repositories is at the US CDC. The other is at the State Research Center of Virology and Biotechnology VECTOR (also known as the Vector Institute) in Russia.

28. Synthesis of genomic material of pathogens could negate the security around the pathogens themselves. As such, the ability of a non-scientist, not belonging to a bona fide research laboratory, to purchase genetic material belonging to the smallpox virus was an eye-opener to both the industry and the security community. Health, research, and security government agencies in the US, in collaboration with DNA synthesis industry representatives, took action to mitigate this potential security vulnerability. The result was a non-regulatory, voluntary screening protocol,¹⁶ which minimizes the security gap, but also ensures economic success of this industry (Figure 12.3). If the screening indicates any uncertainty, the company

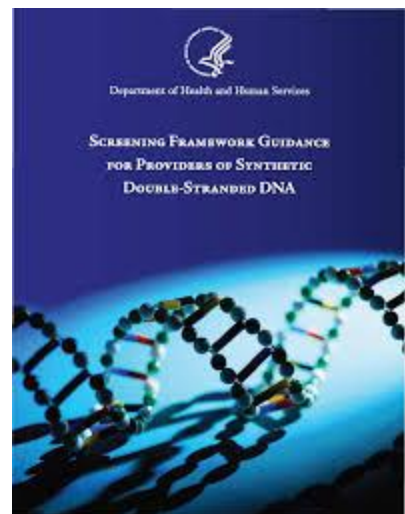



Figure 12.3: Synthetic DNA Screening Guidance

receiving the order contacts their FBI WMD Coordinator to assess the situation, and appropriate measures would be taken. This is an example which showcases how science and security needs can be balanced with societal benefits.

Dual-Use Research

29. States Parties to the Biological and Toxin Weapons Convention (BTWC) have the responsibilities to ensure, through national government action, that their respective scientific communities do not conduct activities pursuant to an offensive biological weapons programme (Article IV).¹⁷ There are provisions within the BTWC that allow activities for prophylaxis, protection and other peaceful purposes. At the same time, the global scientific enterprise has a common understanding of research integrity, as well as the ethos - similar to medical practitioners - of “do no harm”. However, the original purpose and legitimacy of almost any research can be subverted for nefarious purposes, and any research can produce unintended results.

30. The Institutional Biosafety Committees (IBC) (Figure 12.4) in the US are bodies required by the HHS’ National Institutes of Health (NIH) to be set up at institutions that conduct recombinant DNA research. IBCs review projects for health, safety, and environmental implications, and some have recently taken on additional responsibilities to include review of research for dual-use



Institutional Biosafety Committees (IBCs) are the cornerstone of institutional oversight of recombinant DNA research.


<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees>

Figure 12.4: IBC


potential, as well as other security aspects. FBI outreach has built a culture of security among many US institutions. Therefore, they now review research during the entire life-cycle for both safety and security implications.

31. The National Science Advisory Board for Biosecurity (NSABB)¹⁸, established by NIH, continues to look at the dual-use research issue. The NSABB provides a definition (Figure 12.5) with a narrower scope – dual-use research of concern, often referred to as DURC. The DURC definition, could be considered as intentionally open for interpretation. An advantage of this attribute is that it is able to evolve with the body of scientific understanding and advances. Phrases such as “based on current understanding,” “reasonably anticipated,” and “could be directly misapplied” in the DURC

definition provide the flexibility and ability to interpret at any point in time when assessing a research proposal or project.



Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.



<http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>

Figure 12.5: NSABB Definition of DURC

32. General guidelines are provided for the review process, but again they are not prescriptive and allow for flexibility. Continual partnerships among research entities and FBI WMD Coordinators mean that security awareness updates also evolve with changes in the threat spectrum, and so provide for a more complete assessment of DURC.

33. A policy was recently issued in the United States on DURC¹⁹ review which is more specific. This policy focuses on research that uses a subset of pathogens, and on certain types of experiment being conducted. The catalyst for this policy was the two published research articles on avian influenza (H5N1) by Kawaoka and Fouchier, separately. These studies were not the first, and will not be the last, to generate controversy, debate, and concern regarding the safety and security of certain types of research.

34. A meaningful evaluation of the potential security implications of scientific research necessitates the understanding of national, regional, and global risks and threats. It requires the participation of the law enforcement-security sector. This type of communication, at the very

least between the two sectors – research and law enforcement-security - can be very difficult if the participants are meeting for the first time. Factors about the research such as sophistication, uncertainties of outcome, and technical terminologies, could make the dialogue difficult to understand for the national law enforcement and security representatives. Conversely, certain information related to national security risks and threats, especially concerning intelligence, cannot be openly discussed or disclosed. As such, early engagement initiated by either sector can minimize the potential impacts on research and security.

Reaching out to scientists: The International Genetically Engineered Machine Competition

35. The International Genetically Engineered Machine Competition (iGEM) (Figure 12.6) is an exemplar of the degree of advancement and access to research and biotechnology development. iGEM started as a summer course at the Massachusetts Institute of Technology to see if engineering principles can be readily applied to molecular biology. That is, can genes and DNA



Figure 12.6: 2014 iGEM

sequences with known functions be shuffled and arranged to alter, improve, or create novel biological functions or systems. This approach would be synonymous with design of an electronic circuit, using electronic parts of known function. Since its beginning, iGEM has experienced almost exponential growth annually, culminating in 2014 with the participation of over 200 teams, representing almost every continent in a week-long competition. The amazing aspect of this competition is that teams are composed of university undergraduates with a faculty advisor, and there is no monetary award for the winners. There are now also tracks for pre-university and amateur biology teams (Figure 12.7 and Table 12.7) to participate.

sequences with known functions be shuffled and arranged to alter, improve, or create novel biological functions or systems. This approach would be synonymous with design of an electronic



Figure 12.7:
DIYbio

Table 12.7: DIYbio/amateur biology

Who are amateur/do-it-yourself biologist? What do they do?

“DIYbio.org was founded in 2008 with the mission of establishing a vibrant, productive and safe community of DIY biologists. Central to our mission is the belief that biotechnology and greater public understanding about it has the potential to benefit everyone.” <http://diybio.org/>

Individuals who classify themselves as amateur or do-it-yourself biologists are from all walks of life and ages, and conduct science in non-traditional settings. They may be true novices, conducting simple experiments in their homes, using every-day items or used equipment they bought online. On the other hand, they may be classically trained scientists, who want to pursue their own research interests, outside of the work environment, in better equipped spaces. Others may be individuals who are more technically oriented, building tools, hardware and software programs, that support the scientific research.

36. The iGEM Competition is also an example where outreach and awareness at an early point of a scientist’s career can be very effective. The FBI, recognizing the pace of access and speed of



Figure 12.8: FBI outreach at the 2014 iGEM Giant Gymboree

advancements, has been working with the iGEM Foundation since 2009 (Figure 12.8). This demonstrates the bottom-up approach. The FBI and iGEM Foundation interaction started simply with the inclusion of security raising/awareness questions. Since then, there have been teams whose projects’ goals are toward biosecurity improvements (Table 12.8).

Table 12.8: Security Projects from iGEM

2009 PKU Beijing iGEM Team – Human Practices

“As the biohackers are not nearly the mainstreams of researchers, the social attention is not paid enough. However, relevant legislations should still come out soon to prevent potential danger, since the result of our survey shows that as long as one has money, one can get kits and reagents for experiment use. Becoming a novel research fashion to attract broad masses or a facilitated way to produce biochemical weapons? How to use the double-edged sword, the power of decision is held by ourselves.”

2010 Virginia Polytechnics Institute iGEM Team Project

“The GenoTHREAT software is being developed in accordance with the Government guidance and, to our knowledge, is the first implementation of the sequence screening procedure outlined in the guidance. Although software characterization has elucidated both strengths and limitations, GenoTHREAT appears to be a viable tool for sequence screening.”

2013 University of Lethbridge iGEM Team – Human Practices

“It was our goal to investigate the ability of DNA synthesis companies to identify hazardous sequences in their screening procedures in the presence of frameshifting elements.”

Summary

37. This chapter has showcased some of the endeavors undertaken by the FBI to engage the scientific community. Protection of science is of national interest, and requires effort by both the scientific and law enforcement-security communities. There are aspects that are the sole responsibility of the individual sectors. However, there are now more than ever points of intersection, where collaboration is vitally important, especially as advancements in the sciences continue and the global threat spectrum changes. Individuals, groups, and organizations can

make a difference. Taking that first step can seem intimidating, but any effort is better than no effort, and both sectors are trying to achieve a common goal. It starts with a conversation. Trust and understanding can be built from that.

¹<http://law.justia.com/cases/federal/district-courts/FSupp/961/1127/2282702/>

² Larry Wayne Harris: The Talkative Terrorist, Jessica Eve Stern, Published in Jonathan Tucker, ed., Toxic Terror.

Cambridge: MIT Press, 2000.

³ <https://oig.hhs.gov/authorities/docs/05/032905FRselectagents.pdf>

⁴ <http://ilarjournal.oxfordjournals.org/content/46/1/8.full.pdf+html>

⁵ <http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf>

⁶ <http://www.justice.gov/archive/amerithrax/docs/amx-investigative-summary.pdf>

⁷ http://www.nytimes.com/2008/06/28/washington/28hatfill.html?_r=0

⁸ http://www.scienceprogress.org/wp-content/uploads/2009/02/how_scientists_view_law_enforcement.pdf

⁹ <http://www.selectagents.gov/SelectAgentsandToxinsList.html>

¹⁰ <http://www.aaas.org/sites/default/files/reports/AAAS-APLU-AAU-FBI%20report%20on%20personnel%20security%20070114.pdf>

¹¹ http://www.selectagents.gov/resources/Tier_1_Suitability_Guidance_v3-English.pdf

¹² http://unfccc.int/kyoto_protocol/items/2830.php

¹³ <https://www.alliedmarketresearch.com/press-release/synthetic-biology-market-is-expected-to-Reach-38-7-Billion-Globally-by-2020.html>

¹⁴ <http://scienceblogs.com/scientificactivist/2006/06/14/the-guardian-is-able-to-purcha/>

¹⁵ <http://www.dailymail.co.uk/news/article-390703/Lax-laws-allow-purchase-deadly-smallpox-virus-online.html>

¹⁶ <http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf>

¹⁷

[http://www.unog.ch/80256EE600585943/\(httpPages\)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument)

¹⁸ <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity>

¹⁹ <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

Chapter 13: Multisectoral Coordination for Biosecurity Preparedness: a case study on INTERPOL

Guy P. Collyer

Key Learning Objectives

- i. Provide an understanding of the functions of INTERPOL and its Bioterrorism Prevention Program;
- ii. Introduce the elements of biosecurity where law enforcement can play a key role;
- iii. Highlight the critical importance of a multisectoral approach and effective communications;
- iv. Identify future threats and the core principles of biosecurity.

Introduction

1. This chapter will focus on the methodologies used to introduce law enforcement agencies to the challenges they face in developing bioterrorism prevention strategies and policies. For some member countries this may mean the development of strategies and policies that may already be in place. For others it could include a starting point, whereby new laws and regulations need to be developed to support their aims and objectives.

The role of INTERPOL in educating law enforcement agencies

2. Since 2005, INTERPOL has had a progressive BioTerrorism Prevention Program. The primary aim is to assist all of its 190 member countries to have an understanding of the threats and risks associated with biological material being used as a weapon. This does not include the proliferation of biological weapons by States.¹

3. This action was triggered by the anthrax attacks in the USA during the fall of 2001, and complements the global effort to reduce the threat of terrorists using ‘weapons of mass destruction’. To fully understand the development of this programme, it is firstly important to understand the role of INTERPOL, and how it interacts with its member countries.

4. The International Criminal Police Organization, or INTERPOL, as it is more commonly known, is the world’s largest international police organisation, with 190 member countries. Its role is to enable police around the world to work together to make the world a safer place, and to ensure that law enforcement services around the world have access to the tools and services necessary to do their jobs effectively. INTERPOL also has the capacity to provide targeted training, expert investigative support, and relevant data and secure communications channels to its member countries.

5. This combined framework helps police on the ground to understand crime trends, analyse information, conduct operations and, ultimately, bring as many criminals as possible to justice. The aim is to facilitate international police cooperation, even where diplomatic relations do not exist between particular countries. Action is taken within the limits of existing laws in different countries, and in the spirit of the Universal Declaration of Human Rights. INTERPOL’s Constitution prohibits “any intervention or activities of a political, military, religious or racial character”.

Legal Framework²

6. In order to effectively fulfil its cross-border activities, INTERPOL functions under international law. It is recognised as an international organisation by the United Nations. The Constitution is an international agreement that confirms, as members, the governments of all those countries that participated in its adoption in 1956; it also provides the application procedure for countries that were not members in 1956 to join INTERPOL.

7. As INTERPOL's main legal document, the Constitution outlines INTERPOL's aims and objectives. It establishes the mandate of the Organization to ensure the widest possible cooperation between all criminal police authorities, and to suppress breaches of criminal law within a member country.

8. The Constitution defines the structure of the Organization, defines the role of each body of INTERPOL, and provides for the budget and relations with other organisations. Notably, the Constitution specifies that international police cooperation is to be conducted within the spirit of the Universal Declaration of Human Rights. For example, this commitment to human right is expressed through the Organization's cooperation with international courts and tribunals, and through the careful processing of personal data.

Vision and mission³

9. INTERPOL's vision is that of a world where each and every law enforcement professional will be able, through INTERPOL, to communicate securely, and share and access vital police information whenever and wherever needed, ensuring the safety of the world's citizens. There is an emphasis on providing and promoting innovative and cutting-edge solutions to global challenges in policing and security.

Strategic priorities⁴

10. As with all large institutions, INTERPOL remains focused on its strategic priorities, in order to provide the Organization with focus, and to make available a strategic plan for its member countries. There are four key priorities:

- i. Secure global police information systems - INTERPOL has created and deployed a secure global police information and support system that connects all 190 National Central Bureaus⁵ (NCBs), along with other authorised law enforcement agencies and strategic partners, allowing it to instantly access, request and submit vital data.
- ii. 24/7 support to policing and law enforcement - to provide round-the-clock support and a wide range of operational assistance to its member countries, including emergency and crisis response. It is committed to further improving response times, follow-up and the integrated nature of a response. Objectives and activities are focused around supporting the development and capacities of the NCBs, the services provided by the Command and Coordination Centre, the development of new investigative expertise, and the deployment of teams specialised in incident response, security issues at major events and the identification of disaster victims.
- iii. Innovation, capacity building and research - INTERPOL is committed to enhancing the tools and services that it provides in the area of law enforcement training, and to

raising standards in international policing and security infrastructures, whilst remaining committed to delivering high-level training and technical assistance, leveraging on law enforcement expertise and resources.

- iv. Assisting in the identification of crimes and criminals - to provide the highest quality database services, analytical capabilities and other innovative tools to assist in preventing crime, as well as assisting in the identification, location and arrest of fugitives and cross-border criminals. The aim is to further improve the criminal information databases and better support their integration, along with analytical/investigative methods and mechanisms.

The role of INTERPOL in educating law enforcement agencies

11. Strategic Priority 3 makes reference to ‘capacity building’. This is primarily a reference to training law enforcement personnel in best practice over a large range of subjects relevant to their roles. Over recent years the methods used by INTERPOL in educating law enforcement agencies have developed.

12. The use of in-class lectures is now combined with a more dynamic approach, in which table top exercises, live exercises and assisted operations in the field, have become a standard feature of capacity training across all crime areas. This is further supported by the provision of guidance and reference material in hard copy and online learning packages.

13. In areas such as biological terrorism, it is important for INTERPOL to include other key agencies into its training program. Although INTERPOL is there to support the work of its 190 member countries, this frequently includes other agencies relevant to the subject area. In this case, public health and academia have an important role to play in close liaison with law enforcement agencies.

Biosecurity in a changing world

14. Within INTERPOL, the Bioterrorism Prevention Program is located as part of the Chemical, Biological, Radiological, Nuclear and Explosives Sub-Directorate. This in turn forms one section within the Counter Terrorism and Maritime Security Directorate.

15. The possibility of unlawful acts using biological materials represents a growing concern for law enforcement, governments and public health officials around the world. They are considered to be weapons of mass destruction and, as we have seen during deliberate acts as well as natural events, have the capacity to generate widespread fear, significant loss of life and economic loss.

16. Biological materials – such as bacteria, viruses and toxins – are within the environment and, with minimal knowledge, can in some cases be cheaper and easier to produce, handle and transport, than nuclear or chemical materials. They are difficult to detect, and symptoms from exposure may not appear for days or possibly weeks. Once an outbreak of an infectious disease has been established, it can bring pressure upon the most advanced healthcare infrastructures in the world, with the potential in the worst case for societal collapse and civil unrest.

17. Although it has been very rare to see biological materials being used as weapons, such incidents have increased recently.⁶ Even a hoax can be an effective way of instilling widespread fear among the public. As scientific techniques and discoveries rapidly evolve, we need to consider the threats we currently face, and those that may come in the future.

18. By the end of the 1990s, INTERPOL had developed several areas of expertise, but the events of the 11th September 2001 induced the most significant changes the Organization had ever seen in its relatively short history. As well as new command and communication structures and the development of more comprehensive databases able to focus on a wider range of issues, INTERPOL found itself attracting external funders, who had interests in reducing the threat to society.

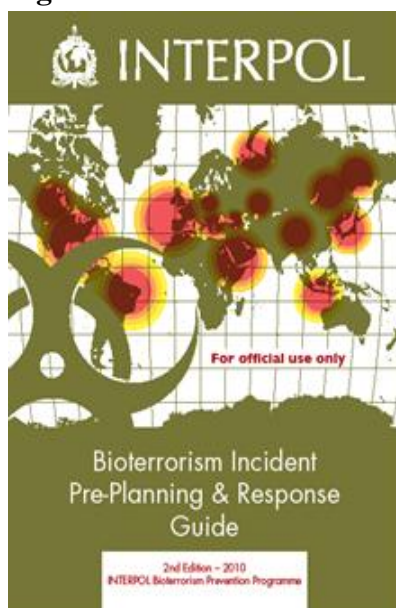
19. In 2004 the Joseph P Sloan Foundation, based in the USA, committed itself to funding a 'Bioterrorism Prevention Program' at INTERPOL. A programme manager was recruited and a global appeal made to law enforcement agencies to assist in the development of a strategic plan and global conference. The first Global Conference on Bioterrorism Prevention took place in March 2005 in Lyon, France, and attracted a significant global audience of senior crime fighters. This conference set the tone for INTERPOL's response in assisting its member countries in reducing the threat posed by terrorists (or others) using dangerous pathogens and toxins as a weapon.

20. The challenge facing INTERPOL was how to deliver this work within the Organization's legal framework and constitution. The first step was to assemble a group of experts from countries that had experience within their own law enforcement community. The first meeting of experts took place in 2006, and consisted of representatives from the United States of America, the United Kingdom, Australia and Canada. Other non-Governmental experts also attended, representing the US Centers for Disease Control (CDC) and the Robert Koch Institute (RKI) in Germany.

21. The most significant outcome of the initial meeting was the recognition that law enforcement could not respond to the threat of biological terrorism on its own, and that other agencies within each country would be vital. Primarily this would involve public health.

22. Whilst initial training programmes and guidance documents focused on the response to a biological incident and the forensic recovery of evidence to assist in the identification and prosecution of the perpetrators of such an event, the introduction and development of countermeasure programmes also became key. With the potential for such a significant loss of life, a strategy was developed for prevention of such events through the use of biosecurity techniques. The 'Bioterrorism Incident Preplanning and Response Guide'⁷ displayed in Figure 13.1 is one product from this work, which remains relevant to date.

Figure 13.1: INTERPOL Guide on Bioterrorism prevention



Integrated policies and practices for a global audience

23. Based on their previous experiences of capacity building and training in the field of Bioterrorism Prevention, in 2013 INTERPOL adopted a new approach towards biosecurity training. This would include a regional multisectoral approach, where law enforcement agencies would work together with the key agencies that would be involved in a biological incident. If INTERPOL were going to demonstrate the value of multisectoral working, the best example they would be able to demonstrate, would be to develop the new programme in partnership with key international organisations or non-governmental organisations.

24. In March 2013 a meeting (also in Lyon) brought together the International Federation for Biosafety Associations (IFBA) and the Connecting Organisation for Regional Disease Surveillance (CORDS). INTERPOL would perform the role of the biosecurity expert, IFBA would maintain the focus on biosafety, and CORDS would highlight the critical importance of disease surveillance. Other international organisations such as the World Health Organization and the World Organisation for Animal Health were consulted, as well as recognised national expert organisations such as the Federal Bureau of Investigation (USA) and Sandia National Laboratories (USA).

Operation S³oMMET

25. The outcome of these two planning meetings saw the creation of what is now known as Operation S³oMMET. The name represents the main aim of the project, which is the Safe, Secure Surveillance of Microbiological Material and Emerging Technology. The project would take the format of a series of regional workshops, which would bring together law enforcement officers, biological safety experts, academic representatives, and public health officials from designated countries within prioritised regions of the world. The main objectives would be:

- i. The assembly of multi-agency representatives to work together in ensuring the protection of the biosciences from malicious activity;
- ii. Allowing INTERPOL member countries a forum in which to raise their concerns and discuss the support they need to improve safety, security and surveillance within the biosciences and related emerging technologies;
- iii. Providing ongoing support and guidance to targeted regions and individual

- countries relating to the safeguarding of the biosciences;
- iv. Empowering the targeted regions to form close links and work more closely together in the future;
 - v. The design and implementation of a comprehensive Programme Evaluation system;
 - vi. Assessing country capacity to support future risk reduction work and identify gaps where assistance can be provided;
 - vii. Laying the groundwork for future work: namely, an additional needs assessment in preparation for Operation S³oMMET Phase 2.

26. During this research many countries confirmed the need for ongoing support. One workshop, supported by an instruction manual, was not seen as being adequate. The pilot for Operation S³oMMET would have a focus on the Middle East and South East Asia. These two regions can be viewed as being very different from each other, but both had seen the emergence of new highly infectious diseases within recent years. From a disease surveillance point of view, this was an important factor. How had the regions coped with identifying and reporting new diseases? How effective were their systems? What lessons had they learnt? The observations from this first phase would provide data that would inform the structure and content of future phases, which would be bespoke for each country.

Planning and Design

27. External experts from key partner institutions were invited to participate in a preparatory meeting at the INTERPOL General Secretariat in Lyon, France. The aims were to design a curriculum and engagement strategy, and to identify and prioritise suitable countries and regions. The meeting was attended by two INTERPOL staff and four external facilitators from the Sandia National Laboratories, Albuquerque, USA; Connecting Organisations for Regional Disease Surveillance (CORDS); International Federation of Biosafety Associations (IFBA); and The Commonwealth Department of Public Health, Australia. Extensive contributions were also made to this process by the US Federal Bureau of Investigation (FBI).

28. Host countries and cities were selected and confirmed. For the first session, three countries in the Middle East region were informed of the programme and invited. For the

second session, ten countries in the South East Asia region were informed of the programme and invited. The different structure for the two workshops would provide valuable data on the best format to use for future workshops. The selection of participants was determined by the respective authorities in participating member states, in line with specific criteria supplied to them by INTERPOL. This was to maximise attendance at the workshop by participants who already had some knowledge of the issues, would be able to assess their national capabilities, and would be able to influence change within their own country.

Selection

29. The INTERPOL National Central Bureaus⁸ were asked to register 8 (in the Middle East) or 6 (in Southeast Asia) high-level participants who were specialised in matters related to bioterrorism, preferably from different agencies.

30. The call for nominations was opened to encompass qualified candidates from the following units:

Senior police officers;

Public health officials;

Biosafety and biosecurity representatives;

Members of the academic and/or the scientific community.

31. Due to regionally specific administrative practices in the Middle East, INTERPOL had to give participating states considerable discretion in the selection of participants, in order to assure the participation of all three countries. The INTERPOL Bioterrorism Prevention Unit chose to invite further individuals from these countries as observers, in order to ensure a fruitful mix of participants and to reach strategic practitioners and decision makers. In South East Asia the organisers were able to suggest participants to NCBs, and thus ensure that the envisioned cross-agency mix of participants came to fruition (Tables 13.1 and 13.2). As a courtesy to the host countries and due to the high interest shown by the local administrations, additional participants from the host countries were accepted for the respective workshops, in agreement with the Canadian Department for Foreign Affairs, Trade and Development (who funded the event).

32. The INTERPOL Bioterrorism Prevention Unit already had some experience of working in the Middle East, and was in possession of useful contacts to assist in arranging the workshop. This was not the case for South East Asia, where it was decided to conduct a brief liaison visit to the host country, to ensure that participants were appropriate and that the correct arrangements were being put in place. This pre-workshop visit proved to be very valuable, and resulted in alterations in logistics, resulting in greater effectiveness.

Workshop Content

33. The agenda for these workshops had been designed at the planning meeting in October 2013. Three elements would be deployed to maximise the usefulness of the workshop for delegates. First, there would be a minimum amount of ‘front loading’ for delegates (whereby they were being talked at rather than taking part in an interactive learning experience). By minimising the number of lectures, delegates would not be subjected to long periods of learning via an interpreter, and viewing PowerPoint slides that were written in a foreign language.

34. The second element featured a three-stage scenario problem-solving exercise that required effective communication between the groups involved, and thus the critical need for a multi-sectoral approach to biosecurity. The positive effect of using this method of teaching included the fact that country delegates who had never met before could now freely interact. They would be learning in their own language and benefitting from the experiences shared by their new colleagues. Over 70% of delegates who attended the first two workshops stated that they had not met their counterparts from other key agencies within their countries before. The workshop was therefore a significant achievement in bringing them together for the first time. INTERPOL frequently use table top exercises (TTX) as one of the most effective and interactive methods of teaching. They promote working together, strong communication and shared accountability, which in a crisis are crucial.

35. Key goals were reached as planned and agreed with the sponsor, the Canadian Department for Foreign Affairs Trade and Development. During the course of the program, 124 participants from 13 countries participated in Operation S³oMMET.

Table 13.1: INTERPOL Operation S³oMMET, Regional Workshop Middle East.
Beneficiaries reached by country and administration⁹

COUNTRY	Biosafety	Law Enforcement	Public Health	Grand Total
Country A	4	1	2	7
Country A (Observers)	1			1
Host Country	4	23	8	38
Country B	3	4		7
Country B (Observers)			2	2
Grand Total				55

Table 13.2: INTERPOL Operation S³oMMET, Regional Workshop Southeast Asia.
Beneficiaries reached by country and administration¹⁰

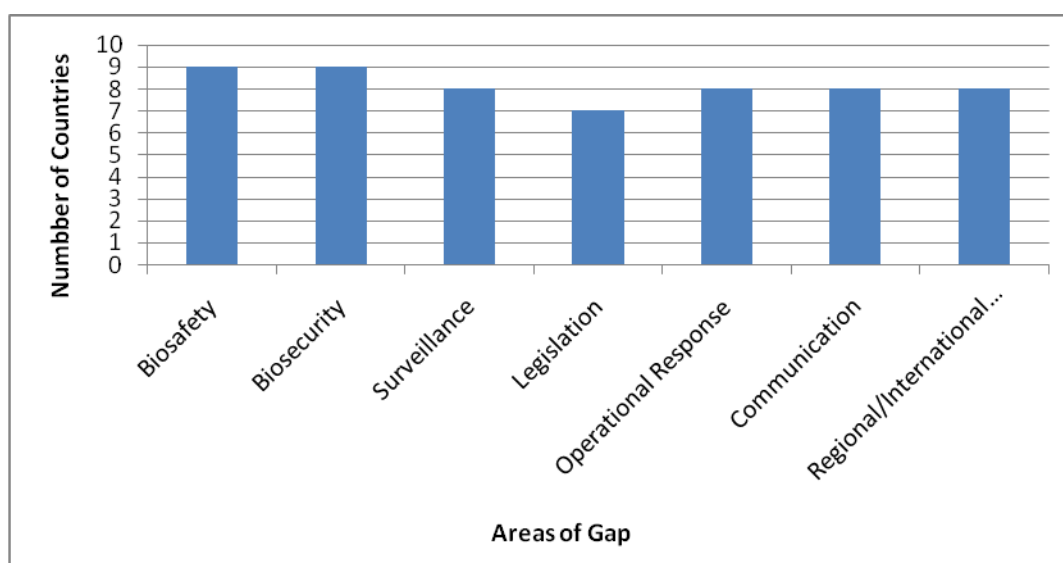
COUNTRY	Biosafety	Law Enforcement	Public Health	Grand Total
Country A	3	2	1	6
Country B	2	2	1	5
Country C	2	2	2	6
Country D	2	2	3	7
Country E	2	2	1	5
Country F	0	2	2	4
Country G	2	2	2	6
Country H	3	2	0	5
Country I	3	2	3	8
Host Country	3	11	3	17
Grand Total	22	29	19	69

Gap analysis

36. Participants at both workshops were asked to fill out confidential forms on the existing biosafety measures and specific needs of their countries. This has enabled the INTERPOL Bioterrorism Prevention Unit to gain an informed view of the biosecurity capabilities in the two regions. This information will also be highly valuable in the development of further capacity building measures for the participating countries, in order to assist them to close identified security gaps and significantly increase biosecurity.

37. The data generated during the gap analysis session is confidential. Countries developed this data to assist in planning their future actions to enhance biosafety, biosecurity and disease surveillance within their own countries. To disclose such material would have an impact on their national security.

Figure 13.2: S³OMMET Gap Analysis



38. Figure 13.2 shows the importance placed on identified gaps during the two workshops. The inference that can be drawn from this is that it is the most immediate and daily risks that participants were most concerned about. Biosafety and Biosecurity are also seen as ‘quick fix’ solutions which can be acted upon immediately. The challenge for such ‘quick fixes’ is the cost. Biosafety and Biosecurity rely on hardware, which is usually very expensive, especially for developing countries where expertise and supplies have to be imported.

39. Legislation had the least amount of interest identified during the gap analysis session. It was seen as a long term measure which would not see any tangible results. The opinion was also expressed that new laws would not stop determined criminals, and therefore the measure would have the least impact on biosecurity. The counter argument was that, if you do not have specific criminal laws with a significant sentence appended to them, how would you successfully prosecute offenders for potentially planning a mass murder?

40. Communication is also an area worth highlighting. As noted above (para. 34), most delegates - and 10 out of the 13 countries that took part in the two regional workshops - stated that they had not met their counterparts from law enforcement, public health or academia, before attending the workshop. Delegates went onto comment that they felt that multisectoral communication was poor within their country and the region.¹¹

Module and Overall Evaluation

41. To monitor Operation S³oMMET, INTERPOL put in place a comprehensive, consistent evaluation system, in order to ensure continuous improvement in the planning and delivery of the programme. This also included the attendance at each workshop of independent observers, who had an established record of expertise in the subject matter.

42. An evaluation form was created to evaluate the usefulness of the workshop, especially module content, quality of visual aids and handouts, and the effectiveness of the instructors. At the completion of each workshop, best practices were added and implemented in the following sessions.

43. The feedback to the first workshop showed that its content was highly relevant to the work of the participants, with 95% confirming this outcome. The vast majority of respondents considered that the workshop achieved its objectives: to have an effective mix of participants, to offer a venue to discuss biosecurity and, to a slightly lesser degree, network with peers in the region. The content and overall quality of the instructors and the event management were highly commended in the feedback: 63% rated the workshop overall very good, 24% excellent and 13% good.

44. Feedback from the second workshop was equally very positive: 78% of participants stated that the course was very valuable to them, and a further 18% described it as valuable. All

participants agreed that the key objectives were met, namely: the selection of participants to ensure multisectoral cooperation, to have an opportunity for discussion, to find sources and for networking to take place with their international counterparts; an overall 49% said that these objectives were fully achieved, and a further 39% said these objectives were achieved to a great extent.

45. This operation was created to enhance the safety, security and surveillance of biological materials and emerging technologies – which have the potential to be used for criminal purposes in regions where there are the greatest vulnerabilities. This may be due to several factors, such as new and emerging infectious diseases being discovered.

Outcomes and Conclusions

46. INTERPOL works on a cycle of continual assessment in what it does, how it does it, and the identification of improvements that need to be made in the work that it does. Operation S³oMMET is part of this process and has taken two distinctive viewpoints, so that the project can continue to evolve into a credible and valuable project.

47. The workshop assessments provided by participants give valuable feedback on how the subject matter experts perform, the structure and content of the workshop, and the amount of benefit gained by each participant. This is further enhanced by the daily assessment provided by an independent observer. The feedback has so far helped INTERPOL in developing or improving:

- a detailed participants' manual;
- role play exercises;
- the current development of an electronic voting system to speed up interactions;
- one-on-one sessions with heads of delegations;
- direct written feedback from each country represented.

48. The Gap analysis data helps to inform INTERPOL regarding the next steps of the project. The data helps to provide INTERPOL with information on where the gaps are, and which training tools would be best employed for a second phase of the project. To date, INTERPOL has conducted a tabletop exercise in one of the participating countries.

49. This exercise, under the heading of S³oMMET II, was designed specifically for the country, taking into account certain features that were unique to it. The scenario included the deliberate introduction of an infectious disease into the most vulnerable part of their society. It tested disease surveillance mechanisms, the police response and investigation of such an incident, and considered future steps to reduce the risks of a biological incident occurring.

50. Future work agreed by participants included the development of a protocol for key agencies in the event of a highly infectious disease outbreak, together with a dedicated quarantine facility and improved screening at border controls.

Future threats and core biosecurity principles

51. The past year has seen a significant increase in the threats and risks associated with the release of biological agents as a deliberate act, whether by terrorists or a lone operator. The issue of securing biological material is more diverse and complex than ever before. Terrorist groups have become larger, more organised and financed in a more sustainable way. Their ambitions appear to be more extreme, as groups such as Islamic State and Boko Haram take control of towns, cities and valuable assets such as oil wells. This is not to mention the plethora of individuals with various agendas, who want to generate fear and cause mass casualty events.

52. In January 2014 a laptop was recovered that contained details of how to acquire bubonic plague and include it in a homemade hand grenade device, that could be used in public areas to kill and infect civilians. In November 2014, in Guinea, a vehicle carrying vials of blood that had been taken from patients suspected to be carrying the Ebola Virus Disease, was held at gun point by unknown persons, and the contents of the vehicle stolen. The vials were not thought to be the target of the armed robbery, but the case highlights the vulnerability of highly infectious biological agents at a time of a significant disease outbreak (see Chapter 5).

53. The following key elements of biosecurity should be considered, taking into account recent events and the continued advance in scientific knowledge, techniques and equipment. These are the core elements of biosecurity but, when implemented, they must be proportionate in relation to the location and risks at the time. Measures should include the ability to increase security as and when the risks change.

54. INTERPOL member countries also need to establish a list of those biological agents they wish to prioritise as at the highest risk from potential misuse. The United States of America¹², the United Kingdom¹³ and many other countries have lists of agents that are considered to be at risk from terrorist misuse. The Australia Group¹⁴ is another international body, which also has a list of agents that are controlled from a counter-proliferation point of view. Once the priority agents have been identified, they need to have enhanced protection.

Physical Security

55. Laboratory biosecurity is important and should be assessed and implemented as part of biosafety procedures. For developed countries, this is little more than an expense, but for developing countries it can be a major issue. Often, buildings are not robust enough to accept security hardware. Fresh water and electricity are rightly seen as greater and more important challenges. The biggest challenge for laboratory biosecurity is to ensure that highly pathogenic material can be protected at low cost, using sustainable methods. There are three key challenges that must be answered to achieve effective biosecurity:

- i. Is the organisation able to account for the pathogens and toxins that it has in its possession? (This must include where they are stored, worked on and disposed of.)
- ii. Has the organisation limited access to them, so that only qualified and experienced personnel can gain access?
- iii. Is the organisation able to tell if anything went missing? (Signs of forced entry? Missing vials? Regular inventory checks?).

56. These features are also part of what is commonly referred to as 'Material Control and Accountability'. Records must be maintained from the moment a pathogen is isolated to the moment it is disposed of. For the highest risk agents (Group 4) this should be witnessed at all times as well.

Information Security

57. As computer anti-virus and firewall software improves, so does the ability of hackers. Access to knowledge and materials for nefarious purposes by non-expert hackers, has also become a lot easier with the 'Darknet'.¹⁵ This was highlighted recently after the arrest of a

man in Liverpool¹⁶, who attempted to buy ricin on the Darknet. Information security is not just about protection of data that is stored electronically.

58. One of the most controversial aspects of biosecurity is the publication of research data. Although it is acknowledged that academic freedom must be maintained, it must always be done taking into account the potential misuse of data, which may expose information on how to increase pathogenicity, how to aerosolise a pathogen, or techniques that increase the ease of misusing biological material for nefarious purposes.

Personnel Security

59. This is another delicate subject within biosecurity teaching. In the early 2000s this subject was taught on the basis of ‘the insider threat’: screening staff and then ‘spying’ on them to ensure they do not suddenly become a threat to biosecurity. INTERPOL has changed the emphasis on such learning, and now places the emphasis on good human resources management.

60. Within a medical or laboratory setting, staff are the most valuable asset. They are well educated and highly skilled, but often poorly paid. It is important to monitor staff performance, so that any issues that may arise are identified at an early stage. Such issues could include financial problems, physical or mental health problems, or other stress inducing situations such as bereavement or relationship problems. If screening methods are put in place to identify any of these issues, managers will also be able to identify someone who may want to use pathogens or toxins for an illegal reason, such as a terrorist act, or even suicide.

61. Screening at the recruitment stage is also critical. There are many guidance documents available online to assist in advising on this.¹⁷ The main emphasis is to check original documents, not photocopies, take up references and consider interviewing the candidate at their home. But this type of screening could be perceived as insulting to trusted staff who have worked for the organisation for many years.

Transfer Security

62. Pathogens and toxins are in transit between different facilities on a daily basis. Such transfers are often governed by national or international regulations.¹⁸ These regulations cover members of the European Union and the United Nations. Transfer security can be a

major challenge, but the basic biosecurity rules apply, about knowing what there is, how much of it is there, checking that access is restricted, and being able to tell if something is missing.

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¹ Article 3 of INTERPOL's constitution does not allow INTERPOL to become in anything related to a member countries politics, including the state proliferation of weapons of mass destruction.

² <http://www.interpol.int/About-INTERPOL/Legal-materials> (accessed 19 June 2015).

³ <http://www.interpol.int/About-INTERPOL/Vision-and-mission> (accessed 19 June 2015).

⁴ <http://www.interpol.int/About-INTERPOL/Priorities> (accessed 19 June 2015).

⁵ Each of the 190 INTERPOL member countries has an INTERPOL office which is referred to as the National Central Bureau. Enquiries and requests should always be made in the first case to a local NCB. The INTERPOL central resources based in Lyon and Singapore exist to support the NCB's in their work.

⁶ In particular, there has been a significant rise in hoax events aimed at embassies in Europe. See INTERPOL monthly CBRNE Digest.

⁷ BIRG Second Edition Published by INTERPOL 2010.

⁸ Representative INTERPOL offices in each of its 190 member countries staffed by persons local to that country.

⁹ These were the findings of the participants who were all provided with a post workshop assessment form.

¹⁰ These were the findings of the participants who were all provided with a post workshop assessment form.

¹¹ Data retained within INTERPOL BTPU 'Op S³oMMET Assessment and Gap Data'.

¹² The USA Select Agents Program is at www.selectagents.gov (accessed 19 June 2015).

¹³ Schedule 5 Anti Terrorism Crime and Security Act 2002 as amended in 2007, <http://www.legislation.gov.uk/ukpga/2001/24/schedule/5> (accessed 19 June 2015).

¹⁴ For more details see www.australiagroup.net (accessed 19 June 2015).

¹⁵ The Darknet is a recently created 'lower level' of the Internet where people can trade anonymously. A specific search engine is required.

¹⁶ 'Terror Suspect "Tried to Buy Enough Ricin to Poison 100 People"', *The Telegraph*, 17 February 2015,

<http://www.telegraph.co.uk/news/uknews/terrorism-in-the-uk/11418146/Terror-suspect-tried-to-buy-enough-ricin-to-poison-100-people.html> (accessed 19 June 2015).

¹⁷ See the various documents available at www.cpni.gov.uk as just one example of good practice.

¹⁸ 'European Agreement concerning the International Carriage of Dangerous Goods by Road', http://www.unece.org/trans/danger/publi/adr/adr_e.html (accessed 19 June 2015).

Chapter 14: The Danish biosecurity system

Robert Petersen

Key learning objectives

- i. Understand how biosecurity is implemented and functions on a national level;
- ii. Discuss the relationship between a national biosecurity authority on one hand, and the scientific community and industry on the other hand;
- iii. Understand the various elements in biosecurity – from physical security to technology control.

Introduction

1. The Centre for Biosecurity and Biopreparedness (CBB) is the national authority entrusted with preventing and responding to biological attacks and accidental releases in Denmark. In this context, CBB is also responsible for maintaining and developing the Danish biosecurity system. This chapter will deal with the origins of Danish biosecurity and how it has developed over the years. It goes on to consider the implementation of Danish biosecurity, address outreach efforts, and understand attitudes in Denmark towards biosecurity. Finally, it considers technology control, research and knowledge, as well as international cooperation.

The origins of Danish biosecurity

2. In June 2014, a 34-year-old Danish citizen was sentenced to three years in prison by a court in Randers, Denmark. According to the court, he had attempted to kill an unidentified person in Ukraine and, for that purpose, he had illegally bought a small amount of the toxin abrin (see Box 14.1), which is very easy to make and very poisonous.¹ Later analysis revealed that it would have been enough to kill between two and 20 persons. The supplier was a 19-year-old male in Florida, USA, who was

selling guns and toxins via ‘Black Market Reloaded’ on the Tor network. The FBI arrested the American supplier in a sting operation and informed the Danish police, who arrested the Danish buyer in January 2014.²

Box 14.1: Abrin.

Abrin is a toxic plant protein extracted from the seeds of the plant *Abrus precatorius*. It can appear as a white to yellowish powder. Abrin, like ricin, causes toxicity by inhibiting the formation (synthesis) of proteins in the cells of the exposed individual. Exposure to even a small amount of the toxin could be fatal.

3. This criminal case highlights the need for a coordinated governmental response, and the difficulties associated with preventing the misuse of biological substances. By an Act of the Danish Parliament in pursuance of United Nations Security Council Resolution 1540, materials that could be misused for the development of biological weapons must be secured against diversion and acquisition for nefarious purposes.

4. The origins of Danish biosecurity can be found in the 1990s. The Cold War had ended peacefully in 1991, but in the following years there was a growing concern that terrorists or ‘rogue states’ would exploit the new world order to develop and use chemical, nuclear or biological weapons. As a response, two Danish working groups – one military and one civilian – were established in the late 1990s, to investigate the threat from biological weapons.³

5. Both working groups finished their reports in 2001, and concluded that there was a genuine threat from biological weapons. Both reports made several recommendations regarding how to establish a biopreparedness capability.⁴ This work coincided with the terrorist attack against the United States on September 11th 2001, which was followed shortly afterwards by the attacks with letters containing anthrax endospores.

6. These circumstances prompted the office of the Danish Prime Minister to grant 15 million Danish Kroner in order to create a national organisation able to respond to biological attacks. The mission statement was to establish a centre for biological preparedness, with the ability to perform biological threat and risk assessment, and

diagnostic investigations; and to provide expert advice and training; and to counter biological warfare agents.⁵

7. The new National Centre for Biological Defence (NCBD) was established at the Statens Serum Institut (SSI - see Box 14.2) in Copenhagen in late 2001. It only had one employee in the beginning (the Director, Dr John-Erik Stig Hansen), but the number would grow to seven employees in 2002. In addition, NCBD established cooperation with 21 military specialists and eight scientists from SSI.⁶

Box 14.2: Statens Serum Institut (SSI).

SSI is a public enterprise under the Danish Ministry of Health. SSI was inaugurated in September 1902 to secure production and supply of anti-diphtheria serum to Danish patients. Today, SSI's tasks include collection and communication of data concerning the health status of the Danish population; ensuring national frameworks and standards for computer technology in the Danish healthcare system; surveillance and control of infectious diseases and congenital disorders; reference laboratories for diseases; ensuring the supply of vaccines; research and development.

From biopreparedness to biosecurity

8. In the years following the events in 2001, it was gradually realised that it was not sufficient to have the capability to respond to a biological attack. It was also necessary to take measures to prevent such a threat from arising. In 2005, the Danish Government decided to create an action plan for fighting terrorism, in the light of recent terror attacks in Spain (2004) and Great Britain (2005). As part of this action plan, a working group was established in October 2005, with a mandate to consider the ease with which terrorists could acquire dangerous substances (radiological, chemical, biological or explosives) in Denmark.⁷

9. The working group published its report in April 2006: one of the conclusions was that, while a strong degree of regulation of explosives and radiological material existed, there was very little regulation of biological substances. The report pointed out that the existing legislation (especially the Danish Weapons Act) was insufficient, and mainly concerned itself with the "end product". In other words, a dangerous

biological substance would not be considered a weapon in itself, and a person stealing a biological substance from a laboratory could only be punished with a fine for stealing. The reason was that biological substances exist in nature, and that technology related to biological substances can serve a legitimate purpose. It was therefore possible for somebody to acquire dangerous biological substances and take the necessary steps to weaponise them, yet only when attached to a delivery system would it become a 'weapon' according to the existing laws.

10. The report also made an important distinction between biosafety and biosecurity. Biosafety rules were aimed at protecting the employees – for example in a laboratory – against accidents. The Danish Working Environment Authority was not entrusted with the task of preventing people from intending to cause deliberate harm using biological substances. Biosecurity – in contrast – aimed at preventing biological substances from being obtained and used to create deliberate harm. The report also pointed out that the UN Security Council Resolution 1540 had made it an obligation for countries like Denmark to enforce effective measures against the proliferation of nuclear, chemical, and biological weapons and their delivery systems (see Chapter 7). For that purpose, the report recommended considering rules for the storing and handling of dangerous biological substances, including how to prevent theft and maintain inventory control. The report also recommended adjustments to the legislation, and the creation of an "advisory and control body".⁸

11. This report coincided with a survey of biosecurity in Scandinavia in 2006, which was described in an article in the journal Biosecurity and Bioterrorism. The survey was divided into two parts: first, a broad questionnaire survey; and second, on-site audits of 22 facilities with 94 laboratories in Denmark. The questionnaire was sent to 109 biosafety representatives in Scandinavia. The questionnaire showed that two BSL 3-laboratories out of 14 reported that their laboratory doors were generally closed, but unlocked during work hours. One laboratory left its doors unlocked after work hours. Three of the 14 BSL 3-laboratories had no locks on their pathogen storage freezers, and only half of the 14 laboratories had an available inventory list that was regularly checked against the actual inventory. The audits showed that, out of ten facilities with dangerous biological substances, only four had perimeter security. 14 out of the 22 inspected facilities had no burglar alarms in the laboratories, although some had

implemented access control and alarms at the external doors to the building. The audits revealed that 50 out of 66 freezers, storing pathogens at 18 facilities, were kept unlocked despite locks being present. The audits also showed that nine facilities storing dangerous biological substances allowed cleaning and service personnel to work unaccompanied and with no security clearance. Pathogens were not routinely accounted for in nine facilities holding dangerous biological substances.⁹

12. All in all, the survey showed a lack of biosecurity, which could make Denmark and other Scandinavian countries a target for illegal acquisition of materials that could be used in a biological weapon. There was also another reason why biosecurity became a serious issue at that time: in October 2004 a Danish company was accused by the CIA of having delivered two spraying devices to Iraq before the fall of the Saddam Hussein regime, and in direct violation of a UN embargo. One of the spraying devices was used by Iraqi scientists at the biological weapons facility Al Hakam, and was discovered by UN inspectors before the site was dismantled in 1996. The Danish authorities launched an investigation: it turned out that the spraying devices had been sold before the UN embargo was implemented in 1990. Nevertheless, the claims were serious and could have created huge financial losses.¹⁰ The case showed that biosecurity was not only about preventing terrorism, but also about preventing proliferation, while at the same time protecting industry from misleading accusations.

13. By 2007-2008, there was a growing consensus that Denmark needed to strengthen the regulation of dangerous biological substances and related materials. On that basis, the Danish Parliament passed the Biosecurity Act in June 2008. 88 members of the Parliament voted in favour of the Act, while 19 voted against.¹¹

The implementation of Danish biosecurity

14. The Biosecurity Act was followed by Executive Order No. 981 in October 2009. The Executive Order sets out the specific regulations for companies who wish to obtain a licence to hold, produce, use and store etc. biological substances, delivery systems, related materials and technology (know-how). The Executive Order also

makes it clear that NCBD, now renamed the Centre for Biosecurity and Biopreparedness (CBB), should be in charge of implementing the Biosecurity Act and the Executive Order. CBB would act on behalf of the Ministry for Health.¹² The new Centre consisted of a section called "Analysis and Biomedicine" (which included a laboratory team); another section called "Biosecurity and Preparedness" (which included a 24/7 field investigation capacity); a "Policy Division" and a Director.¹³ The number of employees grew from about 12 to about 25.

15. As can be seen, the old task of biopreparedness remained, but with some modifications. In the past NCBD had functioned primarily to respond to suspected biological attacks, while CBB was now also tasked with responding to suspected cases of theft, accidents and sudden discovery of dangerous biological substances.¹⁴ Biopreparedness had in 2009 become an entirely civilian task, although many of the specialists had a military background. Biopreparedness now consists of an on-call Field Investigation Team (FIT), which includes a Senior Medical Doctor with specialisation in microbiology. Laboratory analysis takes place in CBB's laboratory facilities, which are manned by a 24-hour duty officer. If necessary, CBB can draw on specialist laboratories with BSL-4 facilities in other countries. In the case of a biological incident, CBB's tasks are to collect information, to take samples, to conduct rapid laboratory analysis, and to provide expert medical advice on relevant countermeasures. An important part of biopreparedness is not only the capacity to respond to a suspected attack, but also to do it in a way that reassures the public and prevents major disruption in society. That could mean the deployment of a FIT without the release of any information to the public, in order to prevent unnecessary fear.¹⁵

16. Biosecurity, on the other hand, demanded the creation of an entirely new organization within CBB. According to the Biosecurity Act and the Executive Order, companies wishing to work with biological dual use components must apply for and acquire a licence. To obtain a licence, a company must meet a set of requirements in accordance with what kind of controlled materials the licence covers. A company with controlled biological substances must, for example, maintain stock management and implement a certain degree of physical security, including an automatic burglar

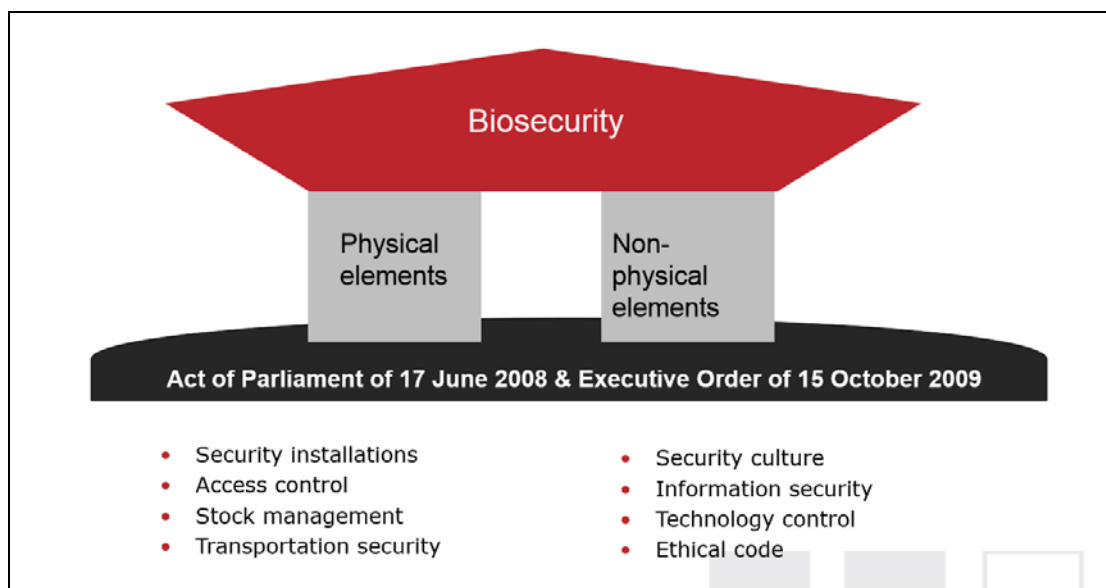
alarm system. All companies with a licence are obliged to have a biosecurity officer (see Box 14.3).

Box 14.3: The biosecurity officer.

In pursuance of Executive Order no. 981 of 15 October 2009, companies are responsible for ensuring that one or more of their employees are appointed as biosecurity officer(s). A biosecurity officer must be employed by the company, and have a relevant educational background. The person appointed is to attend a training course at CBB and, after approval, the biosecurity officer is to ensure that the company fulfills its obligations regarding registration of stocks and training of persons who have access to controlled materials. The biosecurity officer is obliged to keep him or herself updated on biosecurity matters. The biosecurity officer is the company contact point regarding all biosecurity matters, including during inspections.

17. An important principle in Danish biosecurity is that a company with a licence is responsible for its own biosecurity. CBB does not – and indeed, cannot – micromanage every single company with a licence. As Figure 14.1 shows, biosecurity is intended to stand on its own, with two pillars – one consisting of physical elements (like for example physical security or stock management) and the other consisting of non-physical elements like, for example, security culture or an ethical code.

Figure 14.1: The Danish biosecurity model.



18. Although since 2011 CBB has performed a growing number of inspections (five inspections in 2011, five in 2012, 16 in 2013, 18 in 2014, and 30 in 2015), the goal is not to check every single company with a licence, but to ensure that companies understand and follow the biosecurity rules. Not surprisingly, this places a high degree of trust and responsibility on the shoulders of the biosecurity officer. During inspections, CBB will – besides making sure that the rules are adhered to – use dialogue to explain why biosecurity is necessary. In this context it is often regarded as an advantage that the primary inspector is a scientist and able to explain the biosecurity rules. The primary inspector is always accompanied by at least one assistant, who is responsible for taking notes and photos. Only when dialogue repeatedly fails, can it become necessary to enforce the law, suspend the licence and report a company to the police.

Outreach efforts

19. CBB places great value on education and other outreach efforts, in order to increase understanding of biosecurity. CBB offers courses in, for example, ‘responsible science’ for graduate students in life sciences at Danish universities. The objective is to discuss the scientific responsibility for preventing misuse of research results and methods in life sciences. The course includes a historical review of biological attacks and examples of dual-use agents. The emphasis of the course is on biosecurity measures, including strategies for raising biosecurity awareness among colleagues.

20. CBB also has courses in biological preparedness, which are normally offered as either an integrated part of a larger training course or individually, depending on the target group. The target groups are primarily health professionals, decision makers, police and emergency services. Typically, the courses consist of lectures on biological threats and the biological preparedness organisation in Denmark, occasionally supplemented by a two-hour table-top exercise, in which a bioterrorism scenario is analysed and discussed. Furthermore, CBB arranges practical training in incident response in an area where the presence of a dangerous biological agent is suspected,

whether it is an intentional release of biological warfare agents or caused by a laboratory accident.

21. CBB regularly communicates with biosecurity officers via an e-mail newsletter. The newsletter can contain information regarding new national and international biosecurity regulations; information about relevant new publications by CBB; summaries of important biosecurity-related articles; and news about biosecurity in general. The public and the press can also access the website of CBB (<https://www.biosikring.dk/eng>), where they can find information about biosecurity, dangerous biological substances, biosecurity forms etc. The Danish press frequently quoted information from the website during the Ebola outbreak in West Africa in 2014 (see Chapter 5).

22. Finally, CBB also publishes its own information material. In 2013, CBB published a booklet about technology control (see below), and in 2015 CBB published a handbook with a step-by-step description of how to implement biosecurity. The handbook is intended for CBB's international outreach efforts in Africa and elsewhere (see below), and is therefore written in English (see Box 14.4 for pictures).

Box 14.4: Recent CBB publications.



Attitudes towards biosecurity

23. In 2013, CBB decided to investigate the attitude towards biosecurity among biosecurity officers at more than 70 different companies. The company Inter research was hired to circulate a questionnaire, and it received 49 answers from 17 private and 29 public companies. A strong majority expressed the view that the rules in biosecurity were easy to understand – for example, 91 percent believed the rules for acquiring a license were clear. 70 percent considered the amount of time spent on biosecurity as adequate, while 14 percent believed they spent too much time on biosecurity.

24. 65 percent said that the Biosecurity Act had not caused any problems for their company. 57 percent said that the leadership of the companies supported the work of the biosecurity officers, but on the other hand only 18 percent believed their colleagues understood what they were doing. 70 percent described the contact with CBB as good or very good, while only 9 percent described it as bad or very bad. 52 percent expressed the view that working with biosecurity had become easier after an inspection, 17 percent said it had made no change, while 30 percent were unsure. 18 biosecurity officers wrote comments regarding inspections, and most of them were very positive. One biosecurity officer wrote: "I met some very kind and competent persons, who took their time to investigate the facility and to speak with us."

25. As can be seen, a majority expressed their satisfaction with biosecurity. 66 percent believed that biosecurity was important for Danish society, while 27 percent considered it somewhat important, and only 4 percent considered it unimportant. It was only very few who had the same attitude as one responder, who wrote: "I think the Biosecurity Act should be abolished and the money should be spend on something that makes more sense." On the other hand, the user survey also indicated the need for improvements, for example by highlighting the work of the biosecurity officer among co-workers. The most significant need for improvement was, however, related to the difficult question of technology control.

Technology control

26. Back in 2006, the authors of the aforementioned biosecurity survey highlighted that it was not sufficient to focus only on dangerous biological substances and related materials. Biosecurity rules should also include technology – in the form of expertise or knowledge (for example, as documentation regarding an experiment) – that could have a dual-use potential, in accordance with UN Security Council Resolution 1540 and export control requirements.¹⁶ This aspect was included in the Biosecurity Act and in the Executive Order. Companies that are developing technology that can be misused as part of biological weapons development (dual use) must obtain guidance from CBB. In some cases a licence is necessary, depending on the category of the controlled technology (see Box 14.5).

Box 14.5: The three categories of controlled technology.

- A. Technology that, without further modifications, can be used to produce or make use of biological weapons – a licence must be obtained
- B. Technology that has a serious potential for misuse in relation to weapons development – mandatory supervision
- C. Technology that has a less critical and more general dual-usepotential – awareness and biosecurity culture at the company.

27. The question of technology control gained renewed urgency in the light of the H5N1-controversy. In 2011, a Dutch scientist created public uproar when he informed colleagues about a "Gain-of-Function Experiment", which succeeded in creating new contagious strains of the dangerous H5N1 virus (see Chapter 2). The H5N1 controversy resulted in several changes in Danish biosecurity. CBB made it clear in its information to the Danish public that technology with a dual use-potential would require guidance, and possibly a licence. In addition, CBB included the subject in courses for future biosecurity officers and in lectures at universities. Students are particularly relevant for outreach efforts, as they are the future scientists, doctors or health workers. As mentioned before, in 2013 CBB published a short booklet regarding technology, which described what kind of technology could require either

guidance or a licence. All companies in Denmark are also – if it is relevant for them – strongly encouraged to adopt a Code of Ethics for responsible science.

28. Despite all these efforts, the user survey in 2013 showed that 31.8 percent of the biosecurity officers did not know that technology with a dual-use potential could require a licence, and 20.5 percent said that they were unsure what the term "technology with a dual-use potential" was supposed to mean. In 2014-2015, CBB therefore decided to further clarify the rules related to technology control. All companies with an existing licence will in the future have to be reviewed and assessed for work with technology. CBB will also screen grant applications and perform spot checks on scientific publications. Technology control will also play a greater role during inspections. In September 2015 CBB began conducting its first designated dual-use technology inspections.

29. It should be stressed that there is more than one reason behind technology control: the H5N1 controversy in 2011 not only revealed that scientists could conduct research with a strong dual-use potential, but also that the public and the mass media could respond to such revelations with fear and suspicion, which in turn would force politicians to act. Biosecurity is not there to prevent vital scientific work from taking place, but to prevent accidents and deliberate misuse. Ideally, biosecurity will increasingly play a role to ensure public trust in scientific work, thus protecting science from misguided fear-mongering.

Research and knowledge

30. Biosecurity is not only about preventing existing threats, but also understanding where new threats could emerge. CBB is therefore responsible for monitoring new developments that could have an impact on biosecurity. Each year CBB writes a series of internal reports regarding, for example, changes in biosecurity regulations abroad, new threats or new technological breakthroughs. That way, CBB is constantly updating its knowledge, and some of the information is later communicated to the wider public.

31. CBB is also responsible for undertaking research into possible new threats. In recent years, there has been upsurge in criminal cases involving ricin – another simple, yet very poisonous toxin, similar to abrin. In 2013, 11 letters containing ricin were sent to high-ranking officials in the United States, including President Barack Obama. Such attacks are often viewed as more scary than harmful, because it takes skills to purify, concentrate and dry the toxin in a way that makes it lethal by inhalation. That has caused some experts to dismiss ricin or abrin as possible bioweapons.

32. Research and tests by CBB has proven, however, that it is possible for an individual to buy the necessary ingredients to make 1 million lethal doses of ricin using a facility (30 square metres) with running water and electricity. It would only cost about 3,350 USD. If the would-be terrorist would attempt an attack with 1 million doses, and assuming the efficiency of the dispersal would be somewhere between 1 and 10 percent, it would be possible to kill about 1,000 humans in an enclosed space. For around 5,000 USD, with a Ph.D. in microbiology, and with a year of work, it would be possible to make enough lethal doses of a bacterium to kill 100,000 persons, if a suitable seed stock could be acquired.¹⁷

33. The trend in life sciences is currently going in two very different directions that are of concern for biosecurity: on the one hand, the technology necessary to conduct, for example, microbiology is becoming increasingly accessible to a growing number of people, including the ‘Do It Yourself’ community working in private homes. So far, the motive behind ‘Do It Yourself’ has been entirely harmless and benign. There remains, nevertheless, a risk that terrorists or criminals could abuse the ‘Do It Yourself’ community in order to create biological weapons (see Chapter 4).

34. On the other hand, technology is constantly evolving in new directions, and making it possible to revive diseases that have been eradicated (such as smallpox) or create entirely new ones. Such advanced technology will most likely not be accessible for the majority of people, but the risk remains that scientific breakthroughs in life sciences can be misused in order to create new biological weapons. Biosecurity agencies must be alert regarding possible threats from both directions – from ‘below’ and from ‘above’.

International cooperation

35. Globalisation has created new opportunities for those who wish to misuse biological substances, but international cooperation is also growing. In recent years, CBB has taken several steps in that regard. In 2012 CBB, through the Ministry of Foreign Affairs, offered to put its Field Investigation Teams at the disposal of the UN Secretary General for investigating possible cases of biological attacks. Such an investigation could determine if an attack was deliberate, due to natural causes, or if claims of an attack were false.¹⁸

36. In 2013, CBB obtained the necessary funding to implement a project to initiate the establishment of biosecurity in East Africa. The Danish Partnership Programme in East Africa will focus on training and education in relation to biosecurity, assistance in the preparation of biosecurity legislation, and help to create a national authority responsible for biosecurity.¹⁹ Currently the project is concentrated in Kenya, with outreach efforts to the rest of the region. The project is also a Danish contribution to the Global Health Security Agenda (GHSA), which aims to fight infectious diseases all over the world (see Chapter 7).²⁰ The outbreak of Ebola in West Africa in 2014 shows the necessity for such an approach, but there is also a more important long-term issue at stake. Several countries in East Africa are in the process of rapid economic development, but they could be hampered by the threat of terrorism and the inability to import new technology because of the fear of misuse. The implementation of biosecurity in East Africa can reassure international partners that there is a very low risk of misuse of biological substances and related materials.

37. Finally, Denmark is cooperating with other European countries regarding enhancing European biosecurity. The European Biosecurity Regulators Forum (EBRF) is a forum consisting of Switzerland, Denmark, the United Kingdom, Sweden, the Netherlands and France, where biosecurity is discussed and which has produced a report about best practices in biosecurity.²¹ The hope is that EBRF will become a European forum for biosecurity issues.²²

Conclusion

38. There are several reasons why Danish biosecurity could be considered a success, and could help other countries with relevant ‘lessons learned’: first, the Danish system is based on one law and one organisation. This ensures a lean and efficient approach to biosecurity. Second, Danish biosecurity is characterised by using a combination of scientific knowledge and dialogue (including outreach efforts) to make companies or individuals, such as graduate students, embrace and implement biosecurity. This allows for a pragmatic, non-legalistic approach. Third, it has also become obvious that biosecurity can help companies engaged in dual-use research. Fear of modern science is a powerful tool in the wrong hands, and biosecurity can play an important role in reassuring the public. Fourth, biosecurity can also reassure international partners and help mitigate the fear of misuse of biological substances in, for example, East Africa.

39. Biosecurity – in other words – can serve multiple purposes, but the core task remains to prevent the misuse of biological substances. Biological attacks are regarded as low probability, high risk events. Nonetheless, a successful attack could prove devastating, and even the fear of an attack can cause severe disruption in a society. Biosecurity is a national responsibility, but technological developments in life sciences and globalisation mean that it can only work in cooperation with other countries and international organisations. Terrorist groups and pathogens do not respect borders, so in order to prevent man-made biological threats or natural outbreaks like Ebola, it is necessary to work together across borders for the common good.

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⁸ Arbejdsgruppen vedrørende analyse af kontrollen med farlige stoffer, *En analyse af kontrollen med farlige stoffer*, April 2006, page 48-50,

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⁹ Kristian H. Bork et al., 'Biosecurity in Scandinavia', *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 5:1 (2007), page 62-71,

https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Artikler/biosecurity_in_scandinavia.pdf (accessed 2 November 2015).

¹⁰ Lars Halskov, 'PET skal undersøge dansk våbeneksport til Irak', *Politiken*, 19 October 2004; Lars Halskov, 'Minister frikender firma for våben-salg til Irak', *Politiken*, 20 October 2004.

¹¹ *L 69 Forslag til lov om sikring af visse biologiske stoffer, fremføringsmidler og relateret materiale*,

<http://www.ft.dk/samling/20072/lovforslag/169/beh3/forhandling.htm?startItem=2#nav> (accessed 2 November 2015).

¹² *Executive Order on securing specific biological substances, delivery systems and related materials*,

https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Biosikringsdokumenter/en.pdf (accessed 2 November 2015).

¹³ Center for Biosikring og –Beredskab, Statens Serum Institut, *Årsberetning 2009*, page 20, https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Rapporter/aarsberetning_2009.pdf (accessed 2 November 2015).

¹⁴ *Ibid*, page 14.

¹⁵ *Ibid*, page 12-16.

¹⁶ Kristian H. Bork 2007, *op. cit.*

¹⁷ Center for biosikring og –Beredskab, Statens Serum Institut, *Årsberetning 2013*, page 6-7, https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Rapporter/Aarsberetning_2013_web.pdf (accessed 2 November 2015).

¹⁸ Center for biosikring og –Beredskab, Statens Serum Institut, *Årsberetning 2012*, page 21; https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Rapporter/CBB_beretning_2012_netversion.pdf (accessed 2 November 2015).

¹⁹ Center for biosikring og –Beredskab, Statens Serum Institut *op. cit.* (2013), page 20.

²⁰ Center for Biosikring og Bioredskab, Statens Serum Institut, *Årsberetning 2014*, page 19, https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Rapporter/aarsberetning_2014_web.pdf (accessed 2 November 2015).

²¹ EU CBRN action plan, *Guidelines for the implementation of Action B2*, March 2014, https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/External_publications/Guidelines_for_the_implementation_of_Action_B2.pdf (accessed 2 November 2015).

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Chapter 15: Fostering Biosecurity in Jordan

Jwan Ibbini

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Key Learning Objectives

- i. Gain insights into how efforts on biosecurity are organised, despite the presence of current challenges.
- ii. Recognise the development of biosecurity efforts in Jordan.
- iii. Appreciate the importance of national, regional and international partnerships for capacity building and sustainability of biosecurity programmes in developing countries.

Introduction

1. The Hashemite Kingdom of Jordan is a country in the Middle East, bordering Syria to the north, Saudi Arabia and the Red Sea to the south, Palestine and Israel to the west, and Iraq to the east (Figure 15.1). It is located at 31 00 N, 36 00 E, with total area of 89,342 sq. km, the Gulf of Aqaba is Jordan's only port. As of 2010, the total population is about 6,407,085.¹

Figure 15.1: Site map of Jordan²



2. Jordan is moving in the direction of establishing a safe and secure life science culture, despite the presence of several challenges. This chapter is intended to highlight the national efforts to turn biosecurity awareness and preparedness into action, and to highlight the key players in this field today.

3. The geographical location of Jordan puts it in the eye of a political storm in the region. Beginning with the complex situation in Iraq, then the latest Syrian disturbance has greatly impacted the Jordanian infrastructure in several sectors. Hosting large number of refugees in the last four years has led to more intense pressure on Jordan, given its limited resources.

4. The motivation for establishing a biosecurity culture in Jordan results from potential threats, whether they are internal or external, natural or deliberate. The major concern at the moment arises from the community tension posed by the Syrian conflict. The United Nation High Commissioner for Refugees (UNHCR) has revealed that the total refugee population of concern in Jordan is about 630,776 as of 2 November 2015.³ Sources of tension include access to health care and water, solid waste management, and deterioration of education quality.⁴ Therefore, attention should be concentrated on prevention and preparedness in order to enhance competencies with regard to biological security, and to ensure a good response to incidents.

5. At the same time, such regional instabilities have awakened the demand to intensify national efforts in order to manage biological risks from various sources. These efforts need to be coordinated among various stakeholders. Most of the activities are targeting the local community, but they are also building strong networks at a regional and an international

level. Recent international attention has been directed to Jordan as part of the Middle East and North Africa (MENA) region, thus attracting funding for projects that aim to build healthier and more secure communities.

6. This chapter gives an insight into the challenges that affect the progress of biosecurity efforts. It also highlights major elements of concern that needs attention in future, in order to sustain educational activities supporting a biosecurity culture.

Development of Jordan's Biosecurity Programme

7. Jordan's initial role in biosecurity development dates back to 1972, when it joined the Biological and Toxin Weapon Convention (BTWC). Following that, Confidence Building Measures reports were submitted to the United Nations. In addition, Jordan fulfils its obligations under UN Security Council Resolution (UNSCR) 1540, which legally obliges UN member states to enforce protective and effective measures against the proliferation of nuclear, chemical, and biological weapons (WMD).⁵

8. It was not until the beginning of the 2000s that the process of developing biosafety and biosecurity strategies in MENA countries began. In 2007 Abu Dhabi hosted a Biosafety and Biosecurity International Conference (BBIC), during which biological threats in the MENA region and mitigation options were examined. A year later, a framework document was prepared entitled "Developing Biosafety and Biosecurity Strategies for the MENA Region". The Abu Dhabi meeting was followed by a second conference, in Casablanca, Morocco, and a third in Amman, the capital of Jordan, in 2011. A document produced by the International Council for the Life Sciences (ICLS)⁶ summarises the early development of the BBIC meetings. They progressed from examining the biological threats in the MENA region to considering the need to establish national and regional biosafety and biosecurity strategies. The meetings also recommended the development of regional training centres, specifically designed to teach biosafety and biosecurity, working closely with academia, industry and the government. The BBIC has created both national and regional networks, which have initiated several activities in Jordan and other MENA countries. Furthermore, the European Union initiative in the Middle East has led to the creation of CBRN Centres of Excellence in Jordan and Morocco, which aim to reduce biosecurity risks, whether of criminal, accidental or natural origin.

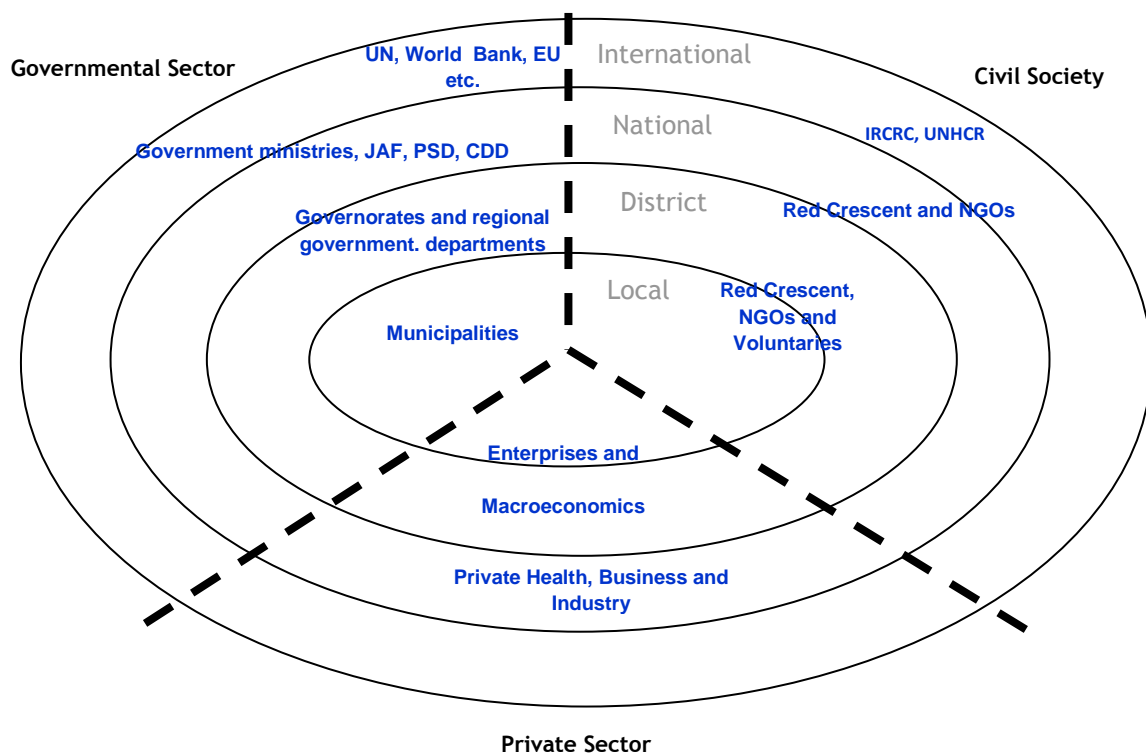
9. Jordan has successfully attracted regional and international assistance, in order to initiate a multitude of activities, focusing on building competence and capacity in relation to biological security. These activities have ranged from biosecurity education and training, to enhancing preparedness and response to incidents.

National Biosecurity Stakeholders

10. The emerging biosecurity concept has been developed by several governmental and non-governmental organisations which, acting in their individual capacity, have initiated a task force, to deal with and control biological risks. This chapter aims to list key players in biosecurity, pointing to an interdisciplinary pool of policy and technical expertise. Figure 15.2 shows the hierarchy of institutional actors during crisis situations.

Figure 15.2: Stakeholders’ involvement during crisis management in Jordan.⁷

Institutional Actors and Stakeholders during Crisis Situations



11. One major stakeholder of biosecurity is the Jordan Armed Forces (JAF) and their Corresponding Royal Medical Services (RMS). The JAF-RMS represents the frontline responder on the borders, and they are continuously seeking to improve their preparedness

and response capacity to deal with biological threats. RMS encompasses specialised centres and military hospitals, covering the country's districts, even in remote areas.

12. On May 2010, His Excellency the Chairman of the Joint Chiefs of Staff approved the establishment of the Arms Control and International Organizations Branch (ACIOB), within the Directorate of International Affairs (DIA), to stand as JAF point of contact. The ACIOB is responsible for following up all treaties and activities pertaining to arms control and weapons of mass destruction (WMD) issues, disarmament and regional security issues, as well as for dealing with domestic and international entities and organisations, in all related CBRN/WMD bilateral programmes, at regional and international levels.

13. Jordan is a State Party to several international arms control and disarmament agreements, such as the BTWC, CWC, the Comprehensive Test-Ban Treaty (CTBT); the Convention on Certain Conventional Weapons (CCW); the Non-Proliferation Treaty (NPT); and the Missile Technology Control Regime (MTCR). Through its different tasks, JAF has also taken a leading role in the implementation of UN Security Council Resolution 1540. The ACIOB is actively involved in all activities related to arms control and disarmament, and combating WMD.

14. The Jordanian Ministry of Health (MOH) bears the major responsibility for providing and supervising the health care system in Jordan. MOH responsibilities include maintaining public health, organising health services provided by the public and private sectors, as well as conducting educational programmes and training. Moreover, the MOH plays an important role through its laboratory directorate of public health and disease surveillance, its crisis management unit, and its newly established emergency operations centre. Recently, the MOH has created a Biorisk Management Coordinator position within the laboratory directorate, tasked with raising awareness among health providers in governmental hospitals, in addition to conducting joint biorisk management activities in collaboration with other stakeholders (e.g. Royal Scientific Society, Jordan University of Science and Technology, Royal Medical Services (RMS), Food and Drug Administration (FDA) and the Ministry of Agriculture). Involving the private sector in implementing biorisk management is essential, but has not yet been achieved. Hence, the MOH has taken the first step in drafting national guidelines for biorisk management. Following the launch of the guidelines, the national Biorisk Management Policy will be formulated.

15. Jordan is implementing the International Health Regulations (IHR) through the active involvement of the Ministry of Health.⁸ In line with the IHR requirements, a national focal point for public health in Jordan has been created. The focal point is responsible for meeting the reporting requirements, confirming public health events of international concern, and assessing and strengthening national capacities. The public health team has dealt with dangerous pathogens such as H1N1, and the Middle East Respiratory Syndrome Corona Virus (MERS-CoV), in collaboration with the CDC lab in the United States, to ensure the proper characterisation of newly emerging pathogens.⁹ Currently, the MOH is monitoring all the activities conducted at the newly installed BSL-3 laboratory.

16. The Princess Haya Biotechnology Centre (PHBC)¹⁰ is hosted by the Jordan University of Science and Technology. It is a leading research centre for diagnosis and training in the fields of genomics, proteomics and metagenomics. The centre is dedicated to increasing the performance and quality of services, through the implementation of the highest international quality standards.

17. With generous grants and direct supervision from the Governments of the United States, United Kingdom and Canada, a BioRisk Management and Genomics Training Division was established at PHBC in 2012, and opened for training on 10 February 2015. The new division hosts the "MiSeq", the first Next Generation Sequencing (NGS) platform of its kind in Jordan. The primary purpose of MiSeq is to facilitate research for pathogen detection and surveillance.

18. The vision of the BioRisk Management and Genomics Training Divisions at PHBC is to establish a sustainable culture of biosecurity in the MENA region, and a training centre that serves the societal needs of Jordan and its neighbours, reduces biological threats to the international community, and strengthens global health and security.

19. The Mission of the MENA Biorisk Management and Genomics Training Division is to:

- i. Enable education of MENA laboratory and clinical practitioners.
- ii. Establish a nucleus for MENA strategic partnership with developed country partners, such as the US, UK and Canada.
- iii. Provide the required technical, managerial and practical knowledge for Biorisk management for people working in different fields of biology, chemistry, healthcare, and medicine.

- iv. Enable the application of molecular detection techniques to the myriad challenges of diagnostic practice, preventive epidemiology, and new biological threats facing Jordan and the MENA region.
- v. Develop and implement biorisk management training courses in order to embed safe and secure life science practices in the MENA region.
- vi. Function as one technical platform to strengthen the partnerships between Jordan, MENA countries and different collaborators worldwide.

20. In recent years, the active role of civil society institutions – which had been previously neglected – has become evident, and the need for cooperative partnerships among different stakeholders is now more appreciated. Credit should be granted to the Royal Scientific Society (RSS), which is a non-governmental organisation that provides testing services and consultation, as well as scientific research. The Jordanian Centre of Excellence in Biosafety, Biosecurity and Biotechnology has been established under the umbrella of the Royal Scientific Society. The Centre’s mission is to strengthen national security, by reducing the risks posed by the potential misuse of life sciences, and the threat from epidemics and other destabilising events, and to improve the nation’s resilience in the face of such events through excellence in training, education and research in advanced biotechnology. Several activities have been conducted in the context of bioethics, biosafety and biorisk management, funded by regional and international agencies. A list of major activities is summarised in Table 15.1.

Table 15.1: List of Activities Carried out by the Royal Scientific Society¹¹

Year	Activity
2015	Daibes, H. (2015) Assessing Biosafety and Biosecurity Practices in the Bioscience Laboratories of Jordan According to the Third Edition of the WHO Laboratory Biosafety Manual (2004). Thesis submitted in partial fulfillment of the requirements for the master’s degree of Environmental Technology and Management; Princess Sumaya University for Technology.
2013	RSS developed an Arabic language training curriculum for biosafety and biosecurity, which is tailored to the needs of the region (funded by the Islamic Development Bank in Jeddah, Saudi Arabia).
2012	The Middle East Regional Secretariat for CBRN Centres of Excellence was hosted in MESIS/Amman.
2012	Since 2012, there have been several initiatives to raise awareness and encourage

to 2015	national laboratories to develop and implement a biorisk management system. Workshops and seminars have been held and organised by the Royal Scientific Society, the Ministry of Health and the Princess Haya Biotechnology Centre, targeting scientists from the health, industrial and academic sectors (from private and public institutions). The workshops explored and discussed the implementation of bioethics, biosafety and biosecurity management systems based on CWA 15793 (2008/2011) and the WHO “Responsible Life Research for Global Health Security” Guidance Document.
2011	3 rd Biosafety and Biosecurity International Conference, Amman.
2010	The Ministry of Health established a Biorisk Management Unit (BMU) to construct a training programme, implement training activities, and start communication with health institutes outside the Ministry, aiming for national implementation of biorisk management systems at hospital laboratories.
2009	Establishment of the National Centre for Security and Crisis Management (NCSCM).
2006	Through the Biosecurity Engagement Program (funded by U.S. Department of State, Bureau of International Security and Nonproliferation, Office of Cooperative Threat Reduction), a Laboratory Biosecurity and Biosafety Workshop was held in April 2006 in Amman, Jordan. Participants were from 15 countries in the Middle East.
2004	A WHO field testing programme for a project on “Guidelines for Assessing National Health Preparedness Programs for the Deliberate Use of Biological and Chemical Agents” was conducted, with technical contributions from various Jordanian ministries (Health, Defence, Interior, Industry, etc.), the Jordanian Red Crescent Society, the Australian Agency for International Development (AusAID), Health Canada, the Organisation for the Prohibition of Chemical Weapons (OPCW), and the United Nations Children’s Fund (UNICEF), as well as different technical programmes from WHO Headquarters and the Eastern Mediterranean Regional Office (EMRO) of WHO.

21. Biosecurity in Jordan also involves the Middle East Scientific Institute for Security (MESIS), which was formerly known as the Cooperative Monitoring Centre (CMC). This is located in Amman and was established as a partnership between the Royal Scientific Society in Jordan and Sandia National Laboratories in the United States. MESIS aims to act as a model to enhance security. The institute provides cooperative technical engagement, and a venue for the exchange of information and the creation of confidence building measures. Furthermore, it continues to promote security in the region, with an emphasis on promoting energy, environment and border security, using science and technology.¹²

22. Another leading NGO is the Eastern Mediterranean Public Health Network (EMPHNET), which was established in 2009 and has its headquarters office in Amman. Its specific focus is the field of epidemiology. EMPHNET recently conducted a pre-conference workshop under the theme of “Promoting “Cradle to Grave” Security of Biological Samples”, prior to the Fourth EMPHNET Regional Conference, that took place in Aqaba, Jordan from 28 September to 1 October 2015. The overall purpose of this specific workshop was to raise awareness of the importance of security of samples and other issues which scientists face in the Eastern Mediterranean Region. This workshop targeted a wide array of health care professionals.

23. During the workshop, a round table discussion was held on promoting “Cradle to Grave” security of biological samples, with a focus on the security of samples, and the shipment of biological and infectious substances. This round table contributed to regional efforts undertaken to raise awareness and increase knowledge in the area of biological sample security. The purpose of this round table was to share and discuss concerns and issues related to the shipment of biological samples; offer an opportunity to gain knowledge on the shipment of biological and infectious substances; allow the participants to learn about relevant guidelines, training materials and certification related to sample security; and contribute to identifying challenges and gaps that might hinder sample security.

24. EMPHNET, in collaboration with the US Biosecurity Engagement Program (BEP), intends to implement a project entitled: “Promoting Security of Biological Samples and Sustainable Sample Management in West Africa.” In particular, the project targets such countries as Guinea, Liberia and Sierra Leone. The project will be implemented in two phases. The first phase aims to promote the security of pathogen samples in the event of biological incidents, “from cradle to grave”, and to support secure and sustainable management of Ebola sample collections. The second phase will integrate training in responsible science alongside technical discussions of sample shipping and transportation to meet the International Air Transport Association (IATA) shipping standards.

25. One key institution that can be actively involved in biosecurity issues with regard to farmland and livestock is the Ministry of Agriculture (MOA). The agricultural sector in Jordan is characterised by unstable production, due to the dependence on rainfall to water the land. The production of ruminant livestock is increasing, with an increase in imported feed. Animal health is an issue of concern, since animal disease is a major cost for livestock

owners. An FAO report states: “The imports of live animals and animal by-products from different parts of the world, and mobility of livestock within and across the borders, increase the potential of infections of animals with epizootic diseases”.¹³ Another institution is the National Centre for Agriculture and Research Extension (NCARE). This governmental institution is responsible for planning, coordinating and implementing research activities in relation to farmland, fodder, livestock and other agricultural sectors. They work closely with farmers and researchers by providing testing services for soil, plants, and livestock.

Jordan’s effort in promoting biosecurity culture

26. With the increased number of life scientists and the advance of biotechnology in many sectors (e.g. medicine, agriculture and environment), there is a need to ensure the safe handling and secure use of bio-agents. At the same time, the sudden increase in population due to human migration from neighbouring countries creates tremendous pressure in the above-mentioned sectors, especially in a country with limited natural resources like Jordan. There is a growing concern about security, which is why Jordan needs to be prepared for addressing potential biosecurity risks.

27. In this regard, both governmental and non-governmental organisations – such as the ones already mentioned in this chapter – have taken the initiative to strengthen biosecurity, with regional and international assistance. National experts have received training both in Jordan and abroad, in order to help organise the nucleus of a biosecurity group, which is intended to facilitate efforts to promote biosafety, biosecurity, and biorisk management.

Events and Activities

28. Several events and activities have taken place in the form of lectures, seminars, workshops and training courses, in order to help build biosecurity infrastructure in Jordan. The activities were led by national experts, targeting a wide array of life scientists in different sectors.

29. RMS plays an integral role in Jordan biosecurity capacity. Enhancing national biosecurity capabilities represents one of JAF/RMS major concerns. JAF acts as the umbrella for national biosecurity activities and efforts, and intersectoral collaboration and coordination are always encouraged. Box 15.1 summarises some of the projects that have been completed, and/or in progress, with many international partners, including the USA and Canada.

Box 15.1. List of some of the activities that are carried out and proposed by the Jordanian Armed Forces and the Royal Medical Services.

Activity
Mobile biological lab in a trailer to detect class A pathogens (Figure 15.3)
Many biorisk (biosafety and biosecurity) events and training courses have been held on RMS campus and off-campus, mainly at Jordan University of Science and Technology, but also abroad, e.g. in Canada and USA.
Train-the-trainer courses for 12 RMS staff on biosafety and biorisk management.
The previously named JAF Crisis Management Center, which was established in April 2002 was renamed as the Directorate of Civil Military Affairs (DCMA) during the opening Ceremony for the new building on the 4 th August 2015 by HE the Chairman of the Joint Chiefs of Staff. The facility was designed and built to be used by the GOJ / JAF, to utilise the assets and capabilities of the Armed Forces to support civilians in emergency situations.
The DCMA unit established a Crisis Management (CM) room, equipped with the necessary communications, to accommodate representatives from both related JAF units and governmental institutions during emergency situations. The project has been funded by the Government of Canada, through the Canadian Global Partnership Program (GPP).
RMS participated at the Global Health Security Agenda (GHTA) Meeting which took place on 19 March 2015 in Nairobi, Kenya. The GHTA is a very promising international initiative, composed of eleven action packages, directed toward preventing, detecting and responding to biological threats.
The Department of Preventive Medicine of RMS held its first international conference on 30 April 2015. The theme of the conference was “Cross Borders, Infections Threats and Challenges”. Several renowned international and national speakers enriched the scientific programme and knowledge exchange.
JAF participated in the 5 th laboratory biorisk management workshop in Winnipeg, Canada from 4 to 7 May 2015.
Two RMS experts participated in the Global Virology Summit with themes of innovations, therapeutic approaches and new rapid technology for viral detection and diagnosis, as well as new strategies for virus control. The Virology Conference was held in Dubai from 27 to 29 August 2015 and was sponsored by US Department of Defense.
Biological and Toxin Weapons Convention (BTWC): JAF has participated actively over the last few years in the Meetings of the Convention on the Prohibition of the Development, Production, and Stockpiling of Biological and Toxin Weapons and on Their Destruction. Many side meetings held on the margins of the Convention have identified projects for enhancing Jordan’s biosecurity capacity.
A project for developing National Chemical, Biological, Radiological-Nuclear (CBRN) Medical Guidelines for Jordan, for dealing with CBRN events and incidents, was submitted by JAF and funded through Canada’s Global Partnership Program; it is a joint Jordanian-Canadian effort. The purpose of this project is to assist JAF-RMS and the Ministry of Health (MOH) to develop regional guidelines and training programmes for medical management of CBRN incidents in Jordan.
JAF is in the process of establishing a CBRN training Centre of Excellence at the Chemical Support Unit (CSU). As part of this effort, JAF finished the first stage by constructing a state-of-the-art CBRN facility within the CSU, with support from the US. The second stage is under process and planning, with assistance and funding through Canada’s Global Partnership Program. It will entail the construction of a CBRN training area, which will be located within the facility. The third stage will take place after completion of the facility. As part of that stage, JAF will proceed to seek accreditation of this facility as a CBRN Centre of

Excellence (Regional and International), with the support of its counterparts from Canada, US and the North Atlantic Treaty Organization (NATO).

Figure 15.3. Opening ceremony for the mobile biological lab on the 13 November 2014. Top photo shows HE Bruno Saccomani Ambassador of Canada and RMS representatives. Bottom right shows vehicle exterior, and bottom left shows the glove box inside the vehicle.¹⁴



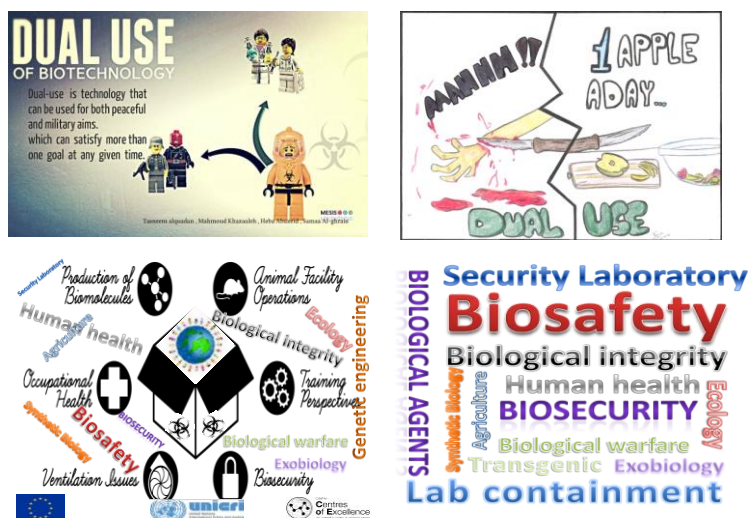
30. Two trainers in the Ministry of Health have received a licence from the WHO office, and started to train biorisk management officers in many health care facilities in government labs. Besides training courses, five biorisk management workshops have been conducted in the past three years. The trainers have further conducted field visit evaluation, and communicated extensively with health care providers to facilitate the implementation of biosecurity.

31. The staff at Princess Haya Biotechnology Centre have received extensive training in biorisk management, both on the Centre's premises in Jordan and at Sandia National Laboratories in the United States. Four staff members are licensed Sandia biorisk trainers. The Centre is heavily involved in biorisk management and genomics training. Since January 2010 the following events have taken place at the centre: 23 workshops on Biorisk Management, 22 workshops on Polymerase Chain Reaction, 4 workshops on Basic Laboratory Equipment Maintenance and Repair, 1 workshop on Microbiology, and 1 workshop on Pathology. The different workshops included participants from the following countries: Jordan, Iraq, Yemen, Libya, Algeria, Egypt, Afghanistan and Pakistan.

32. The Princess Haya Biotechnology Centre has also conducted a series of meetings and workshops in collaboration with the American Association for the Advancement of Science (AAAS). One such workshop was titled “International Engagement: Responsible Science for a Safe and Secure Society”.¹⁵ The goal of the workshop was to encourage collaboration between biological scientists from the United States and the United Kingdom, and participants from 13 countries of the broader MENA region. Topics covered at the meeting included the state of scientific and human capacity, and responsible stewardship. Scientific collaboration offers significant opportunities to advance biological science, to address national priorities, and to discuss shared principles and standards of practice.

33. One objective is to incorporate biosecurity into academic curricula, just as bioethics has been integrated into the education of medical students. A workshop was carried out through Project 18, ‘International Network of Universities and Institutes for Raising Awareness on Dual-Use Concerns in Biotechnology’ within the framework of the EU CBRN Centres of Excellence initiative. The workshop aimed to engage undergraduate students with biosecurity and dual-use issues in the life sciences.¹⁶ The activity took place at the Hashemite University, and was jointly organised by MESIS and the Centre of Excellence in Biosafety, Biosecurity and Biotechnology. Students were introduced to the topics through an interactive team based learning approach (see Chapter 20). Students’ involvement and participation was enthusiastic, and they gave positive feedback about the organisation, subject matter and learning outcomes. After the workshop, the students were asked to design educational posters about dual use to pass the knowledge to their fellow students. Some of the students’ posters can be seen in Figure 15.4.

Figure 15.4: Educational posters prepared by students¹⁷



34. A recent Master's thesis entitled "Assessing Biosafety and Biosecurity Practices in the Bioscience Laboratories of Jordan According to the Third Edition of the WHO Laboratory Biosafety Manual (2004)" was produced under the supervision of Dr Nisreen Al Hmoud at Princess Sumayya University. The study aimed to assess the level of biosafety and biosecurity practices in Jordanian bioscience laboratories, in order to help reduce the likelihood of accidental exposure of staff or the environment to biological agents, and to minimise the risk of malicious misuse of pathogens or toxins. In summary, the study emphasised the importance of having national legislation as an infrastructure for effective and sustainable biosecurity programmes in bioscience laboratories. The study further proposed a multi-disciplinary approach to biosafety and biosecurity training initiatives aimed at the Jordanian biosciences community.

Progress of biosecurity in Jordan in relation to international regulations

35. In response to biosecurity initiatives, Jordan has been able to make contributions in the following domains:

1. International Health Regulations (IHR)

A mission for the assessment of IHR core capacities took place in Jordan from 22 to 26 January 2012. The main objectives of the mission were to:

- i. Identify the core capacities required to support IHR implementation at the local/community level and/or primary public health response, and at the intermediate and national levels.
- ii. Provide guidance on the use of assessment tools.
- iii. Identify ways to integrate the IHR requirements into existing public health laws in Jordan;
- iv. Agree on IHR core capacity requirements for points of entry in the country.

2. *Biological and Toxin Weapons Convention (BTWC)*

- Jordan became a State Party to the BTWC in 1972, and has submitted Confidence Building Measures reports.
- National implementation of the BTWC in Jordan has been achieved through the development of a penal code, export control and environmental legislation.

3. *United Nations Security Council Resolution (UNSCR) 1540 (2004)*

- Jordan has been conducting a comprehensive review of legislation relating to the implementation of the UNSCR 1540, particularly the laws and regulations dealing with export control.
- In 2005, Jordan submitted a report on the status of its national legal infrastructure concerning Weapons of Mass Destruction (WMD)-related materials. The report stated that Jordan is ready to cooperate with countries which are able to provide assistance, in terms of either legislation or operational skills and resources.

Challenges and the future of the biosecurity programme in Jordan.

36. This chapter discusses the efforts made to accelerate the development of biosecurity in Jordan, and the challenges that were noted during the implementation of biosecurity activities. One major question that arises in the context of Jordan, and perhaps in that of other neighbouring countries, is how to secure the life science sector and monitor its development, given the ongoing unrest in the Middle East. Moreover, hosting large number of refugees demands attention in several sectors, above all education, health care and security. This is a challenging burden for a country with limited resources such as Jordan, which requires external assistance and funding to maintain stability.

37. Given the growing number of life scientists and those working with biological materials in Jordan and the MENA region, sustainable educational programs in biosafety, biosecurity and dual-use are required. Although good biosafety practices are implemented in diagnostic and research labs, biosecurity culture is still lacking. In general, the progress on the ground has not yet moved beyond training and capacity building among users. Until national strategies and firm regulations are set and implemented, a bottom-up approach to education and awareness-raising needs to be followed.

38. Perhaps one of the major challenges facing the sustainability of biosecurity projects is the limited availability of funding, enabling project activities to continue only within the duration of the project. Other challenges may include the lack of coordination among funding agencies, inadequate means of evaluating project success and the effectiveness of programmes focused on prevention, and overlapping activities among biosecurity stakeholders. In addition, the absence of national strategies and a framework tailored for biosecurity make it difficult to mandate the implementation of biosecurity measures in any organisation.¹⁸

39. Anwar Nasim *et. al* wrote in this regard: “Any enterprise, to be effective, must be built on a framework appropriate for the goals of the enterprise and the region. Depending to a great extent on the resources and political climate, the framework on which a life sciences enterprise is built will include, to varying degrees, human resources, technologies, finance, patent law, marketing, management, and safety and security programs tailored to the needs of the enterprise”.¹⁹ An additional challenge arises from the low availability of training materials in Arabic addressing biosecurity principles. The Islamic Development Bank in Jeddah, Saudi Arabia has supported the RSS in developing Arabic training material and a curriculum for biosafety and biosecurity that is tailored to the needs of the region. And finally, the biorisk management infrastructure is still under construction, and will require more effort in the coming years.

40. Some concerns have been identified by the Ministry of Health,²⁰ including the unsatisfactory communication they have experienced with the private sector, and with the veterinarian labs. Inadequate financial support for educational and training programmes was also highlighted.

41. As a recommendation, it is necessary to undertake a comprehensive national risk assessment for biosecurity that would clearly state the sources of threats. National priorities

and needs should then be identified, in accordance with the country's policies and resources. The progress achieved in the area of biosecurity in Jordan so far gives reason for optimism. With sustained financial support, educational activities can be enhanced to meet national requirements and plans for development. Such activities could generate a national code of conduct on biosecurity, that can be used to upgrade the educational material used in seminars and training materials related to biosecurity and biorisk management. When safety and security become part of the culture among life scientists, and when all the "Soup" (Figure 15.5) ingredients complement each other in a holistic approach, then biosafety and biosecurity will be effective and sustainable.

Figure 15.5: The life sciences enterprise "Soup"²¹



"The "Soup Slide" was developed spontaneously during discussion at the MENA region meetings. Biological safety and security must be part of the "soup" of our life science enterprises."

42. Attention must be given to the agricultural sector as a major stakeholder in biosecurity development in Jordan. Input from the Ministry of Agriculture and its associated laboratories for testing and research is very valuable, and complementary in ensuring both plant and animal health security. The National Centre for Agricultural Research and Extension (NCARE) is a leading institute for agricultural research for the optimal use of available resources to achieve sustainable agricultural growth.²² It is therefore recommended that they contribute to establishing national biosecurity guidelines and legislation.

Conclusion

43. Jordan has recognised the need to ensure secure use of biological materials, especially at a time of political instability in the surrounding region, in order to prevent and respond to biological incidents of accidental or deliberate origins. Since 2009 the emergence of national centres and institutions capable of carrying out a variety of relevant activities and initiatives has successfully established an effective network of experts from different sectors, both nationally and regionally. These networks can influence decision-makers to push forward the establishment of a national strategy for biosecurity, and offer potential contributions toward implementation of UNSCR 1540 obligations.

44. So far, most efforts have been directed into awareness-raising, training, capacity building and policy development, mostly carried out with external funds. These funds are valuable for sustaining these activities in the region, and for sharing knowledge and expertise that will enhance local, regional and global security. However, local and regional efforts to sustain such activities show that there is interest in biosecurity within the region. Some key lessons learned from regional cooperation and national efforts could be summarised as follow:

- i. National efforts revealed that biosecurity initiatives need to be complemented by national policies, to ensure proper implementation of biosecurity.
- ii. A national committee of an interdisciplinary team of experts should be formed, in order to build a national and international network for information exchange and response.
- iii. More attention needs to be given to prevention and preparedness in Jordan.
- iv. Biosecurity in Jordan should expand to include other stakeholders, particularly with reference to agricultural and environmental enterprises, as well as border security.
- v. It is necessary to keep active regional connections and relations in order to ensure proper dialogue during biosecurity incidents.

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<http://www.moh.gov.jo>

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<http://www.just.edu.jo/Centers/PrincessHayaBiotechnologyCenter/Pages/MENABioriskManagementTrainingDivision.aspx>

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<http://www.fao.org/ag/AGp/AGpC/doc/counprof/PDF%20files/Jordan.pdf>

¹⁴ The Mobile Biological Lab is a kind donation from the Canadian Department of Foreign Affairs Trade and Development (DFATD) to the Jordan Armed Forces Royal Medical Services (JAF-RMS) of up to 1,000,000 CAD.

¹⁵ AAAS/JUST workshop report, “International Engagement: responsible Bioscience for a Safe and Secure Society,” <http://www.aaas.org/sites/default/files/reports/AAAS%20JUST%20report.pdf>

¹⁶ To learn more about the COE initiatives refer to chapter 6.

¹⁷ Four out of six posters presented by students following the workshop on dual use of biological material at the Hashemite University in Jordan, as part of Project 18 activities.

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²⁰ Based on personal communication with Dr. Tariq Sannouri and Mrs Ghaya Al-Wahdane from the Ministry of Health.

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Chapter 16: National implementation of biosecurity in South Africa

Louise Bezuidenhout

Key learning objectives

- i. Trace the bioweapons programme, Project Coast, developed by the Apartheid Government of South Africa;
- ii. Highlight the key roles that individual scientists, together with poor governmental oversight, played in the development of Project Coast;
- iii. Discuss the efforts made to develop biosecurity in post-Apartheid South Africa, with particular reference to the important role played by scientists in developing this approach;
- iv. Understand the challenges of developing robust biosecurity regimes in low/middle-income countries.

Introduction

1. An analysis of biosecurity in South Africa offers two important contributions to contemporary discussions. First, as a country that covertly developed and then voluntarily disbanded a bioweapons programme, South Africa offers an important historical case study into how changing times are driving a constantly evolving and adapting approach to biosecurity control. In the first part of the chapter, South Africa's historical involvement in biosecurity is examined in detail, highlighting lessons that may be learnt about national implementation of biosecurity programmes.

2. Second, the current South African approach to non-proliferation demonstrates the power that government commitment and an involved scientific community may have in changing regimes and combating bioweapons development. Nonetheless, despite

the considerable advances made by South Africa in the years since democracy, challenges still exist. One such challenge is the need to raise awareness of biosecurity issues amongst the scientific community. The second part of the chapter examines the changing biosecurity regime and the continued challenges of raising biosecurity awareness in South Africa – with particular reference to its status as a low/middle-income country. The chapter concludes with some comments on the key role that scientists play in the maintenance of biosecurity regimes.

Learning from the past – Project Coast and bioweapons development in Apartheid South Africa

3. Starting in the 1940s, the South African Government developed a system of racial segregation known as Apartheid, which was enforced through legislation. Since its conception there was widespread international condemnation for the Apartheid regime, and in the subsequent decades this led the Government to develop a heightened sense of isolation¹ and to increasingly distance itself from the West.

4. Apartheid was also met with significant internal and external resistance – including arms and trade embargoes against South Africa, and widespread internal violence. Together, this resistance made it difficult for the Government to maintain the regime. This led the Apartheid Government to support the development of weapons that would defend the white elite from their perceived enemies. As a result, from the 1960s to the 1980s the Government invested in research into nuclear, chemical and biological weaponry.

Developing a bioweapons programme: World Wars to Project Coast

5. Prior to the start of the chemical and biological weapons programme in the 1980s, South Africa already had considerable experience with chemical and biological weapons. Its involvement in the two World Wars,² and the threat of chemical and biological weapons faced by their soldiers during these conflicts, had led South Africa's scientific and military community to be one of several national communities that “kept pace with developments in chemical and biological weapons during the

inter-war years”.³ As quoted by Purkitt and Burgess: “by the end of the Second World War, the South African policy makers learned from experience that biological weapons were a simple technology that anyone could use and that it could be effective in Africa, under certain conditions”.⁴ Such expertise was further enhanced during the 1960s and 70s, when the South African Government had increased support and involvement in counter-insurgency programmes in several neighbouring states. This allowed the South African military the opportunity to explore the potential usefulness of unconventional chemical and biological weapons.⁵

6. In the 1970s, South Africa was becoming increasingly embroiled in military engagement in Angola⁶ against the Soviet-backed SWAPO, Cuban and Angolan troops. The Soviet Union was known to possess nuclear, biological and chemical weapons (see Chapter 3), and South African officials had “gained some indication of the scale and sophistication of the Soviet programme during and after negotiations surrounding the 1972 Biological and Toxin Weapons Convention”.⁷ In order to counter the perceived threat of enemies with access to battlefield chemical and biological weapons, the South African Government initiated measures to produce equipment for defensive purposes – including masks and protective suits, as well as research on vaccines.

7. As the years progressed, however, the activities of this programme diversified and research was carried out into the offensive uses of the newly found capabilities. In 1981 this emerging offensive focus was officially sanctioned by then-president PW Botha, who requested the South African Defence Force to further develop technologies, so that they could be used effectively against South Africa’s enemies. The South African Defence Force commissioned the head of its Medical Service division,⁸ Dr Wouter Basson, to form Project Coast in 1983 (see Box 16.1).⁹

Box 16.1: Wouter Basson.¹⁰ (Source <http://www.iol.co.za/news/crime-courts/basson-to-defend-his-licence-1.1144552#.VToWOrFwaUk>)

	<p><u>Dr Wouter Basson</u> (1950 -) Trained as a cardiologist and served as personal physician to Prime Minister P.W.</p>
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Botha. Became the head of Project Coast and implemented the Apartheid Government's chemical and biological weapons programme.

Was investigated by the Truth and Reconciliation Commission in 2002, but acquitted of 46 counts of murder, conspiracy, drug possession and fraud, and granted amnesty. The presiding judge drew attention to the poor quality of the State's prosecution and inability to convince the court of Basson's guilt in a manner "beyond reasonable doubt".

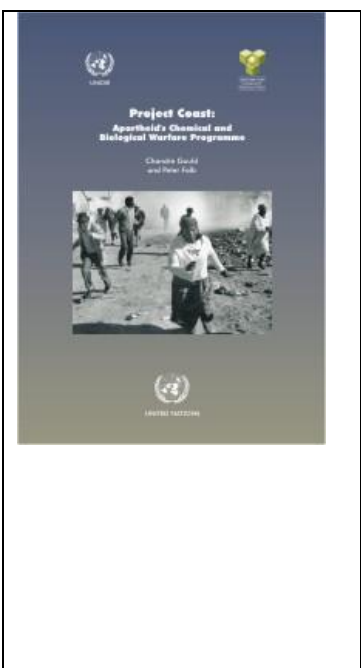
In 2013 the Health Professions Council of South Africa found Dr Basson guilty of unprofessional conduct. A hearing is currently underway to decide whether to strike Dr Basson off the medical registry.

8. The location of Project Coast within the South African Defence Force Medical Service allowed for a highly secret and loosely managed organisational context, in which Dr Wouter Basson exercised considerable personal influence over the direction of research.¹¹ Moreover, in order to conceal the intentions of the programme - as well as the procurement of reagents important in chemical and biological weapons production – four separate front companies were formed.¹² In addition, a number of different research and testing centres at universities and companies, in various parts of the country, also assisted in Project Coast research.¹³ The highly secretive and distributed organisational structure, together with the considerable personal control of Dr Basson, became key factors in the direction and nature of the research pursued by Project Coast.

9. In its years of activity, Project Coast (Box 16.2) developed and manufactured a large variety of lethal offensive chemical and biological agents, intended for use in military combat as a last resort. A variety of pathogens, including those that cause

Anthrax, Cholera and Botulism, were collected and/or developed during this time. Many of the means of delivery of agents developed by Project Coast were designed to look like ordinary objects, such as umbrellas, walking sticks and screwdrivers – an approach pioneered by the Soviet bloc – with capabilities to be used for assassinations.

Box 16.2: Project Coast: Apartheid’s Chemical and Biological Warfare Programme¹⁴

	<p><u>Project Coast: Apartheid’s Chemical and Biological Warfare Programme</u></p> <p>Chandre Gould and Peter Folb</p> <p>This book offers a detailed explanation of how the Apartheid Government in South Africa created the Project Coast programme – how they acquired the knowledge and materials to develop these weapons, and how the programme eventually closed. It is an excellent resource for anyone wanting an insightful examination into South Africa’s history in biological and chemical weaponry.</p>
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10. In contrast to the chemical and biological weapons programmes of many other countries, however, a considerable focus was also placed on the development of non-lethal agents to help suppress internal dissent.¹⁵ Increased domestic political unrest and opposition to Apartheid¹⁶ stimulated considerable research and development of “exotic means to neutralize opponents, large-scale offensive uses of the programme”, and “weaponisation”.¹⁷ This led to the investigation of unusual non-lethal agents - both illicit recreational drugs (such as MDMA – 3,4-methylenedioxy-methamphetamine or ecstasy, methaqualone and cocaine) and medicinal drugs (including diazepam, ketamine, suxamethonium and tubocurarine) - as potential incapacitating agents. It was intended that these agents could be weaponised through aerosolisation, so that they could be released over crowds as riot control agents.

11. Moreover, the racism doctrine of the Apartheid regime led to support by Project Coast for genetic engineering research. Although details of this research remain elusive, it is known that some research was focused on creating a 'black bomb', with the intention of using bacteria or other biological agents that would selectively target black individuals.¹⁸ Better known are Project Coast's attempts to selectively control black fertility, as part of efforts to limit the growth of the black population.

Disbanding Project Coast and the Truth and Reconciliation Commission

12. In February 1990 the South African Government unbanned the African National Congress and other political parties and organisations opposed to Apartheid. This marked the beginning of a 4-year process to end the regime. In March of the same year, the then-president FW de Klerk ordered that no lethal chemical agents should be produced by Project Coast.¹⁹ The 1993 signing of the Chemical Weapons Convention (CWC) was closely followed by the alleged destruction of the drugs and chemical agents produced by Project Coast.

13. On the 27th of April 1994 South Africa held its first democratic elections, in which the African National Congress won a sweeping victory, with 62% of the vote. As part of the reconciliation process, the new government instituted the Truth and Reconciliation Commission (TRC), a court-like restorative justice body, to address crimes relating to human rights violations, as well as reparation and rehabilitation. The 1998 public Commission hearing into Project Coast has been a key source of information about the activities of the programme.²⁰ Witnesses who gave evidence included former staff, as well as Dr Wouter Basson and the former Surgeon General, Daniel Knobel. This public hearing was the first of its kind in the world and, as Gould and Folb state: "Nowhere else had a government or military establishment been required to account openly and fully to the public for the development and daily activities of a national chemical and biological weapons program".²¹ This hearing raised a number of key issues (summarised in box 16.3).

Box 16.3: Systemic issues that contributed to the development of Project Coast.

What issues assisted Project Coast activities?

- i. Political climate of fear and perceived justification for the development of weapons for ‘defensive’ purposes.
- ii. Poorly delineated control and supervision, allowing Dr Basson a high degree of autonomy.
- iii. Development of private companies frustrated need for transparency and scrutiny.
- iv. Recruitment of scientists on a ‘need to know’ basis disguised extent of project activities.

14. First, although Project Coast was ostensibly under the control and supervision of the military, in reality it was largely designed and executed by a single individual - Dr Wouter Basson.²² The weaknesses in the management of the programme may largely be attributed to the location of Project Coast within the South African Defence Force Medical Service; this had important consequences, as the Medical Service existed as a separate medical branch of the South African military, with joint ties with Special Forces. This provided a highly secret and loosely managed organisational context for Project Coast, in which weak oversight and accountability led to personal abuse of authority and corruption.²³

15. Second, although Project Coast was claimed to be strictly defensive in nature, it went far beyond the strict constraints of a defensive programme.²⁴ The evidence from the Truth and Reconciliation Commission showed that Project Coast was neither “purely defensive nor oriented solely towards external threats”,²⁵ despite South African Defence Force officials repeatedly stating that Project Coast was established to counter the threat of chemical and biological weapons in Angola. The use of front companies – and their eventual privatisation – exacerbated the fine line that exists between defensive and offensive research, and emphasised the critical need for transparency and scrutiny.

16. Third, in the management of the programme, scientists recruited from universities and other institutions conducted their work on a strict ‘need to know’ basis, an arrangement that appeared to make possible flagrant violations of ordinary professional ethical behaviour.²⁶ Moreover, Project Coast was intellectually challenging and appealing to many Afrikaans scientists, who “shared a sense of patriotic duty, a nationalistic zeal for the importance of the work, and a sense that their research was critical for maintaining national security”.²⁷ Together, this created a situation in which many scientists were manipulated into contributing to projects that might have given them cause for concern, had the full details been known.

17. Finally, the contrast between the outputs of Project Coast and the commitments made by South Africa to international conventions, such as the Biological and Toxin Weapons Convention (BTWC), showed disregard for the international treaties that normally constrain national chemical and biological weapons programmes.²⁸ In justifying these violations, the Government undoubtedly drew on its increasingly paranoid perception of national security and threats to the sovereignty of the country. These acts, as suggested by Purkitt and Burgess:²⁹ “support a more general proposition; regimes already isolated in the international community will continue to violate their commitments to international law, as perceived threats to their survival grow”.

18. Without the national and international oversight possible with transparency and openness, the activities of Project Coast were able to continue largely unimpeded. The extent of these activities, as revealed by the Truth and Reconciliation Commission hearings, shocked many South Africans, and stand as an important lesson for all those engaged in teaching about chemical and biological weapon development.

A changing nation: biosecurity in post-Apartheid South Africa

19. In the years since democracy, scientific research and development has seen significant developments in South Africa. In 2013, for instance, the Scientific American Worldview Global Biotechnology report³⁰ ranked South Africa 36th overall of 53 countries in terms of biotechnology. This score was based on a number of

different categories, including intellectual property, intensity, enterprise support, education, foundations, policy and stability. It scored particularly well on intellectual property and enterprise support.

20. The Government has been active in attempting to assist advances in biotechnology, particularly through the development of a National Biotechnology Strategy (2001)³¹ to guide the modernisation of the Government's biotechnology institutions, and to identify methods to further develop the existing industry in response to a changing political and technical environment. Key attention has been paid to the ways in which biotechnology may contribute to national priorities, such as health (e.g. HIV/AIDS, malaria and tuberculosis), food security and environmental sustainability.³²

21. Although innovations to encourage private research and development have seen this sector increase substantially, the majority of life science research and development activities in South Africa remain in public institutions. Of these, public universities lead the publication output through research, while the country's research councils and industrial establishments also produce a number of publications on biotechnology.³³ South Africa has by far the highest research output on the continent, and thus serves as a regional hub for collaboration and support.³⁴

A commitment to biosecurity

22. In addition to stimulating growth in the biotechnology sector, the post-1994 Government of South Africa has also been firmly committed to a policy of non-proliferation, disarmament and arms control, covering all weapons of mass destruction. In keeping with this policy, the country has become an active participant in the various non-proliferation regimes,³⁵ and adopted positions publicly supporting the non-proliferation of weapons of mass destruction, thus contributing to the promotion of international peace and security. The Government has also put considerable effort into strengthening national legislation surrounding biosecurity.

Commitments to non-proliferation and national legislation

23. As mentioned above, South Africa has been a State Party of the Biological and Toxin Weapons Convention since 1975, the Nuclear Non-Proliferation Treaty since 1991, and the Chemical Weapons Convention since 1997. Since becoming a democracy, the Government has put considerable effort into developing comprehensive legislation aimed at preventing the misuse of biological (and chemical and nuclear) materials.

24. In keeping with its commitment towards non-proliferation,³⁶ South African law “prohibits any person, whether for offensive or defensive purposes, to be or become involved in any activity or with goods that contribute to weapons of mass destruction programmes”. Furthermore, it forbids any person to be or become involved in any dual-use goods or activities that could contribute to weapons of mass destruction.³⁷

25. Acts such as the Non-Proliferation of Weapons of Mass Destruction Act 1993 (Act No. 87 of 1993)³⁸ address issues relating to such weapons, as well as South Africa’s obligations to non-proliferation through export control regimes. As part of this Act, all facilities that have listed agents or equipment are required to register with the South African Council for the Non-Proliferation of Weapons of Mass Destruction (‘Non-Proliferation Council’).

26. One of the technical committees of the Non-Proliferation Council is the Biological Weapons Working Committee, which is composed of representatives of the various government stakeholders and expert bodies involved in biological-related controls, manufacturing, use and distribution, including the Agricultural Research Council, the Department of Health, higher education institutes, the Industrial Biotechnology Association of South Africa, the National Institute for Communicable Diseases, Protechnik Laboratories,³⁹ and the South African Defence Force Medical Services. The Committee advises the Non-Proliferation Council on issues related to chemical and biological weapons, and the implementation of biological controls.

27. Within the framework of biosecurity, South African legislation covers a range of activities relating to the possession and transportation of agents, licensing of facilities

and persons handling agents, and border controls. In addition to this growing body of legislation, the South African Defence Force has also made a commitment to abstain from the acquisition and deployment of weapons of mass destruction.⁴⁰ This commitment also extends to the acquisition, development or use of biological non-lethal weapons.

Outbreaks and containment

28. In order to be able to address biological threats (natural or non-natural), South Africa has developed considerable mechanisms to deal with detection, protection, decontamination, and treatment of biological threats. In such situations the South African Defence Force Medical Services works in cooperation with the Department of Health and the Department of Agriculture, when dealing with situations with a distinct biological threat. Since 2006 a set of standard operational procedures has been in place to govern the joint management of incidents involving biological or chemical agents, or radioactive material.

29. South Africa has also recently invested in biological and chemical defence equipment and research. The majority of this investment is directed towards chemical defence equipment, such as detection hardware and decontamination systems. However, there are also activities focusing on the detection of biological warfare agents and other biological compounds, technical support for weapons of mass destruction non-proliferation treaties, and data collection and maintenance of an information database on biological weapons.

Scientists in South Africa's biosecurity regime

30. Scientists have played an important role in the development of South Africa's biosecurity regime. In particular, the Non-Proliferation Council's Biological Weapons Working Committee is a good example of how scientists from diverse institutions and disciplines (agriculture, health, and industrial biotechnology, from government institutions such as higher education institutes, the private sector and the Defence Force) contribute towards the development of robust non-proliferation policies. In addition, scientists have formed part of South Africa's delegations to the Biological

and Toxin Weapons Convention, and thus played a key role in the country's continuing commitments to strengthening the BTWC, and supported efforts aimed at realising a strong, effective and universally accepted Convention.⁴¹

31. In addressing these areas, South Africa has demonstrated its commitment not only to non-proliferation, but also to ensuring that the measures are in proportion to the national perceived threat, and that they are implementable, cost-effective, and sustainable. South Africa has been vocal in support of the development of non-proliferation strategies that are suitable for use in low/middle-income countries, and that do not hamper economic development.

32. Through these efforts, South African has played an important role in developing a regional perspective on non-proliferation, and raising awareness of the need to formulate guidelines and set up initiatives concerning biosafety and biosecurity. In addition, South African professional organisations have started to play an important role in raising national and regional biosecurity awareness. In particular, the Academy of Science of South Africa has been influential in critically assessing the current state of biosecurity awareness amongst South African scientists (as described below), and positioning biosecurity issues on discussion agendas.

33. In addition, the 2013/2014 prosecution of Dr Wouter Basson for unprofessional conduct (see Box 16.1)⁴² by the Health Professionals Council of South Africa has placed discussion of Project Coast back on the national agenda, and contributed to a raised awareness of the need for a robust biosecurity regime.

Continuing challenges: raising awareness

34. Despite the considerable involvement of scientists in South Africa's developing biosecurity regime, concerns remain regarding the extent of biosecurity awareness amongst scientists 'in the labs'. Similarly to many other countries, biosecurity training has not been formalised within South Africa. Training in biosafety, biosecurity and bioethics is most commonly developed and administered 'in house', and may vary considerably between institutions. Similarly, the extent to which these topics are addressed in undergraduate and postgraduate curricula differs amongst teaching

institutions. As a result, the life science community of South Africa – like many other countries – may be suggested to have highly variable levels of biosecurity awareness.

35. Without a comprehensive understanding of the levels of biosecurity awareness amongst scientists, it is difficult to speculate on how effectively they will engage with biosecurity legislation, perpetuate biosecurity practices within laboratories and raise biosecurity concerns. This, it is easy to see, may have implications for the robustness of any non-proliferation strategy.

36. In response to these concerns, the Academy of Science of South Africa launched a multifaceted project in 2013, to critically examine the current state of biorisk management in the South African life sciences.⁴³ As part of this study, a survey was administered to life scientists working in public and private research facilities.⁴⁴ This survey was an adapted version of a World Health Organization (2010) survey entitled ‘Responsible life sciences research for global health security,’⁴⁵ designed to canvass perceptions and understanding of biorisk management amongst life scientists.

37. The results of the survey highlight some of the concerns about biosecurity awareness. In particular, the survey raised awareness about problems relating to biosecurity education, and a perceived absence of communication between governmental policy makers and the scientific community. Some of the key findings from the survey are detailed in Box 16.4.

Box 16.4: Key issues raised by the 2013 Academy of Science of South Africa survey.

Key issues raised by the Academy of Science of South Africa survey:

- i. Scientists reported low levels of biosecurity training and education on key issues such as dual use.
- ii. Perceptions exist within the scientific community of a lack of communication between policy makers and scientists.
- iii. Overall lack of awareness amongst professional scientists of measures in place to protect whistleblowers.
- iv. Need for harmonisation of institutional biosecurity measures.

38. Such surveys demonstrate the continuing need for raising biosecurity awareness amongst scientists, and that biosecurity awareness cannot be presumed within the science population, despite the existence of comprehensive legislation. Identifying these issues provides a good baseline for future educational initiatives, enhanced strategies to protect whistleblowers, as well as enhanced communication strategies between policy makers and scientists.

39. As within the ‘web of prevention’ model, scientists play an important role as the ‘first line of defence’ in raising concerns about their own research – and that of others. Enhancing efforts to make scientists aware of key legislation, to make the legislation applicable (and implementable) in the working environment, and to protect anyone who would raise concerns, is thus vital for robust biorisk management, in which scientists play an effective role in mediating against biosecurity concerns.

Challenges for biosecurity education in South Africa

40. Improved biosecurity education amongst the scientific population is an obvious necessity in South Africa. Nonetheless, roll-out of education in the country has been hampered by the same problems experienced around the world – namely, slow and patchy implementation, and a lack of resources, coordination and strategic planning. Furthermore, the ‘bottom up’ nature of most educational initiatives, together with the preference for short-term projects and/or extremely broad curricula, has added additional complications (for additional discussion refer to Chapter 19).⁴⁶

41. These issues are further compounded when considering low/middle-income countries such as South Africa. Severely limited funds for research and teaching institutions, low resourced environments, and highly burdened higher educational systems, create further challenges to implementing biosecurity education. Moreover, contextual variations in culture, societal preferences and priorities potentially limit the ease with which educational material can be transported to these countries from their high-income counterparts, and often necessitate considerable contextualisation (as demonstrated in Box 16.5). In the following section some of these issues are examined in detail.

Box 16.5: Vocabulary issues can confuse biosecurity education in South Africa.

Confusing vocabulary ...

Within South Africa, governmental publications and the national press predominantly use the term “biosecurity” to refer to agricultural security relating to animal and foodstuffs. Consequently, “biosecurity awareness” – even amongst the scientific community - may not automatically be taken to refer to laboratory security, and may in fact refer to agricultural control of genetically modified organisms or the control of animal diseases.

Finding funds for biosecurity education

42. Despite the considerable financial resources that the South African Government is directing towards biotechnology, it is unlikely that much of this money will be earmarked for bioethics training (including biosafety and biosecurity). Indeed, such a situation is complicated by the tendency to allocate these funds to specific research projects addressing national priorities, such as human health (HIV/AIDS, malaria and tuberculosis), food security and environmental sustainability,⁴⁷ making it difficult to see where the funds for developing biosecurity curricula may be sourced.

43. Moreover, as with most low/middle-income countries, this situation is compounded by a scarcity of pedagogues qualified to teach such courses. Bioethics remains a small field in low/middle-income countries, and South Africa is no exception. Most biosecurity training is dependent on the existence of ‘champions’ within an institution, who personally take on the pedagogical challenge. The recognition of the need to support these ‘champions,’ and to increase the capacity of qualified teachers, has led to a number of international ‘train-the-trainer’ schemes, that have already demonstrated some success.⁴⁸

44. While short-term funding for curriculum development, pedagogue training, and workshop roll-out has provided some exposure, the effects of these activities are often short-lived due to chronic underfunding and lack of national support. The lack of the continuing resources necessary to support any long-term educational activities in

South African institutions continues to be a key ‘rate limiting’ step, that presents a continual challenge to the development of capacity in most low/middle-income countries. Efforts to secure long-term funding, which will allow for extensive curricula development and roll-out, will be vital to improving biosecurity awareness in these regions.

The need to contextualise the problem

45. Recent interviews with scientists in South Africa⁴⁹ have elucidated that many scientists struggle to balance the contrast between the perceived low threat of bioterrorism and the overwhelming ‘on the ground’ threats to human health (such as HIV). In such cases, biosecurity issues such as dual use may be dismissed as a “Western problem”, and one that has little relevance to scientific research in South Africa.

46. Such studies highlighted not only that the perceptions of ‘threats’ and ‘benefits’ of research vary considerably around the globe, but also that contextual sensitivity is a vital component of effective engagement and education. Rolling out biosecurity education in low/middle-income countries (LMICs) must thus be recognised as not simply being a case of importing modules and case studies ‘wholesale’ from Western countries,⁵⁰ or simply modifying case studies to make them contextually relevant. Indeed, careful attention is needed to adapt them, so as to reflect and the address the concerns and preferences of the countries in which they are to be implemented.

47. Ensuring that discussions and ethics education reflect responsibilities for scientists that are both feasible and logical to implement in their research environments is also important for ensuring engagement and compliance:⁵¹ this establishes the vital link between behaviour in the laboratory and expectations beyond the laboratory door. As yet, scientists from LMICs are often under-represented in international biorisk discussions. While concerted efforts are being made to facilitate their inclusion, it is vital that their contributions are not curtailed as a result of these international discussions maintaining too ‘Western’ a perspective, or focusing predominantly on the developments in ‘high tech’ science (as described in Chapter 19). In order for international biosecurity discussions to be maximally robust, space needs to be made

for LMIC scientists to not only voice their concerns, but represent their daily research pressures and priorities.

Learning lessons from South Africa

The key role of scientists in biosecurity regimes

48. Project Coast highlighted the need for widespread accountability and awareness in scientific research, in order to avoid situations in which offensive bioweapons research may continue largely undetected. It also highlighted the importance of ensuring that the scientific community – and civil society – are not in possession of information on a ‘need to know’ basis, but instead have a broad understanding of the life science activities occurring in the country.

49. The post-Apartheid Government has made considerable efforts to include scientists in the development of a robust biosecurity regime. Indeed, ensuring the involvement of representatives from multiple sectors of scientific activity has proven a key asset for the Non-Proliferation Council. Nonetheless, despite the considerable progress made by the post-1994 government in advancing a non-proliferation agenda, many of the activities have been confined to high-level policy development. Dissemination of these issues to individual scientists has relied largely on the compliance of institutions with national legislation, and awareness raising activities within these individual institutions.

50. As illustrated by the findings of the survey by the Academy of Science of South Africa, such dissemination pathways are neither efficient nor effective, and awareness of biosecurity issues remains low amongst the scientific population – as have discussions regarding the role that the scientific community can (and should) play in strengthening the Government’s commitments to non-proliferation. In particular, the absence from national science curricula of discussion about Project Coast or the activities of the post-1994 Government appears to be an overlooked opportunity for building a robust and engaged scientific community.

The need for oversight

51. Both the development of Project Coast and the post-1994 non-proliferation stance emphasise the crucial role that national governments play in biosecurity control – how perceptions of national threats and priorities are balanced can, as demonstrated, yield markedly different biosecurity regimes. Understanding what regimes view as threats, and how they justify their response to these threats, are critical elements of chemical and biological weapons scholarship.

52. One of the most important lessons to be taken from the Project Coast case study is that, unfortunately, being a State Party to any treaty cannot be taken as an infallible sign of compliance with it. While the Apartheid Government was a State Party to both the Geneva Protocol and Biological and Toxin Weapons Convention, its activities were contrary to these commitments. This provides an important example of how commitments to international treaties need to be backed up by activities that demonstrate intention. In this, the post-1994 Government provides an excellent counter-example, incorporating these commitments into national legislation, and using their membership of various international bodies to further promote their non-proliferation commitments.

53. Evidence from the Truth and Reconciliation Commission strongly emphasises the importance of transparency and multifaceted oversight in any chemical and biological weapons activities, so as to ensure that the commitments made by the government are upheld. Indeed, keeping the majority of the South African population – scientists, society and indeed governmental officials – in the dark over Project Coast enabled its activities to proceed largely unimpeded. Studying the South African example thus highlights the important role that scientists play in surveillance and whistle-blowing, as they form a vital element of a robust ‘web of prevention’.

The future for South Africa

54. The activities of the post-1994 democratic government illustrate the marked difference that a change in regime and priorities can have on biosecurity management. In the 20 years since the end of Apartheid the South African Government has built up

a comprehensive body of legislation safeguarding biosecurity, and positioned itself as a champion of non-proliferation in the international community. In this, the power of political will and commitment cannot be overestimated.

55. The changing political will, international support, and dedicated resources have allowed modern South Africa to make comprehensive steps towards addressing elements of the ‘web of prevention’ model discussed in Chapter 7. This has occurred through improving legislation and regulations, as well as addressing export controls, disease detection and prevention, and oversight of research. Furthermore, the recognition of the need to also improve biosecurity awareness and education amongst the scientific community, will undoubtedly assist in furthering South Africa’s strong commitment to biosecurity.

References

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² South Africa had close ties to the United Kingdom and was a member of the western alliance.

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⁴ Ibid, p. 230.

⁵ Ibid.

⁶ “The collapse of Portuguese colonialism during 1974 – 1976 led to the takeover of Angola and Mozambique by revolutionary communist regimes, backed by the Soviet Union and Cuba”, Ibid., p. 235.

⁷ Ibid, p. 235.

⁸ The South African Medical Service division was already responsible for the defensive chemical and biological weapons capabilities developed.

⁹ Gould, C. and Folb, P. I., *Project Coast: Apartheid’s Chemical and Biological Warfare Programme*, United Nations Publications, 2002.

¹⁰ People’s Health Movement – South Africa, ‘Dr Basson guilty of unprofessional conduct’, available at <http://phm-sa.org/accountability-for-apartheids-agents-why-dr-wouter-basson-deserves-to-be-struck-off-the-medical-register/> (accessed 22 June 2015).

¹¹ Purkitt, H. E. and Burgess, S. 2002, op. cit.

¹² Delta G Scientific Company, Roodeplaat Research Laboratories, Protechnik and Infladel. At the time there were sanctions in place against the sale of military-related items to South Africa. Gould, C. and Folb, P. I. 2002, op. cit.

¹³ Purkitt, H. E. and Burgess, S. 2002, op. cit.

¹⁴ Gould, C. and Folb, P. I. 2002, op. cit.

¹⁵ Gould, C. and Folb, P. I. 2002, op. cit.

¹⁶ A state of emergency was declared in South Africa in June 1985.

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¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid.

Gould, C. and Folb, P. I., 'The South African chemical and biological warfare program: an overview', *The Nonproliferation Review/ Fall-Winter 2000*.

²¹ Ibid.,p. 10.

²² Gould, C. and Folb, P. I. 2002, op. cit., p. 21.

²³ Purkitt, H. E. and Burgess, S, op. cit.

²⁴ Gould, C. and Folb, P. I. 2002, op. cit., p. 21.

²⁵ Gould, C. and Folb, P. I. 2000, op. cit., p. 11.

²⁶ Gould, C. and Folb, P. I. 2002, op. cit., p. 21.

²⁷ Purkitt, H. E. and Burgess, S, 2002, op. cit.

²⁸ Gould, C. and Folb, P. I. 2002, op. cit., p. 22.

²⁹ Purkitt, H. E. and Burgess, S, 2002, op. cit.

³⁰ 'Scientific Worldview: A global biotechnology perspective,' *Scientific American*, 2014, available at www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/ ([accessed 22 June 2015](#)).

³¹ http://www.esastap.org.za/download/sa_biotechstrat_jun2001.pdf (accessed 12 February 2015).

³² 'A National Biotechnology Strategy for South Africa', available at www.esastap.org.za/download/sa_biotechstrat_jun2001.pdf (accessed 12 February 2015).

³³ Pouris, A. and Pouris, A., 'Biotechnology research in South Africa: a benchmarking exercise,' *Journal of Business Chemistry*, January 2009, available at www.businesschemistry.org/article/?article=31 (last accessed 22 June 2015).

³⁴ <http://www.elsevier.com/online-tools/research-intelligence/research-initiatives/world-bank-2014> (accessed 12 February 2015).

³⁵ This was decided by the South African Cabinet on the 31 August 1994. See Abdul Samad Minty, 'Statement to the Conference on Disarmament', 1 September 2011, www.dfa.gov.za/docs/speeches/2011/mint0901.html (accessed 12 February 2015). South Africa has also committed to using its membership in organisations such as the Non-Aligned Movement and the Africa group to promoting the importance of non-proliferation.

³⁶ Meek, S. and Stott, N., *Destroying Surplus Weapons. An Assessment of Experience in South Africa and Lesotho*, United Nations Publications, 2002.

³⁷ Bezuidenhout, L. (2014a), 'Country Report: South Africa' in McLaughlin, K. et al. (eds.) *BioWeapons Monitor 2014*. BioWeapons Prevention Project.

³⁸ Other important acts include *Agricultural Pests Act 1983* (Act No. 36 of 1983); *Animal Health Act 2002* (Act No. 7 of 2002); *Defence Act 2002* (Act No. 42 of 2002); *Hazardous Substances Act 1973* (Act No. 15 of 1973); *Health Act 2003* (Act No. 61 of 2003); and, importantly, the *Protection of Constitutional Democracy against Terrorists and Related Activities Act 2004* (Act No. 33 of 2004).

³⁹ Protechnik Laboratories ... was established as a private company in 1986 to develop defensive equipment against chemical weapons and was later connected, together with Roodeplaat Research Laboratories and Delta G, to Project Coast – Apartheid South Africa's chemical and biological warfare (CBW) programme. In 1996, Protechnik was acquired by the

State agency, the Armaments Corporation of South Africa Ltd. (Armcor). Purkitt, H. E. and Burgess, S. 2002, op. cit.

⁴⁰ Bezuidenhout, L. 2014a, op. cit.

⁴¹ Statement of South Africa to the Meeting of States Parties to the BWC, 11 December 2012, [www.unog.ch/80256EDD006B8954/\(httpAssets\)/D14D43B22B1DE71FC1257AD100528BDE/\\$file/BWC_MSP_2012-Statement-111212-AM-South+Africa.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/D14D43B22B1DE71FC1257AD100528BDE/$file/BWC_MSP_2012-Statement-111212-AM-South+Africa.pdf) (last accessed 22 June 2015).

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⁴³ ASSAf (2015) *The State of Biosafety and Biosecurity in South Africa*. Academy of Science of South Africa, Pretoria, May.

⁴⁴ 300 scientists from both public and private research facilities in all 9 provinces participated in the survey.

⁴⁵ http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en/ (accessed 12 February 2015).

⁴⁶ For an extensive discussion, see chapter 21.

⁴⁷ Bezuidenhout, L. 2014a, op. cit.

⁴⁸ As discussed in chapter 2 1.

⁴⁹ Bezuidenhout, L. (2014b), 'Moving life science ethics debates beyond national borders: some empirical observations', *Science and Engineering Ethics*, 20:2, 445 – 467.

⁵⁰ Ibid.

⁵¹ Bezuidenhout, L. (2014c), 'Ethics in the minutiae: examining the impact of daily laboratory processes on ethical behaviour and ethics education', *Science and Engineering Ethics*, Feb 9 [Epub].

Chapter 17: National implementation of biosecurity in Canada

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Key learning objectives

- i. Understand that the integration of biosecurity best practices into a broader framework of biosafety can lead to comprehensive national oversight programmes.
- ii. Understand the complexity of developing modern legislative and regulatory authorities.
- iii. Understand how to effectively communicate between governmental agencies, and develop relationships and networks of support.
- iv. Develop appreciation of the challenge of incorporating safety and security into the current culture of science, and how strengthening accountability at institutional levels can be a catalyst for change.

Introduction

1. Canada has national oversight systems in place for the safe use and secure laboratory containment of human and animal pathogens, as well as plant and aquatic pathogens. This chapter will highlight Canada's implementation of biosecurity as it relates to Risk Group 2, 3, and 4 human pathogens and select micro-biological toxins. National risk management and oversight for these types of pathogens is the responsibility of the Public Health Agency of Canada.¹ While Canada recognises that research and diagnostic work with human pathogens and toxins is paramount to public health, science, and innovation, it is also accepted that this

important work poses risks to public health and safety that need to be addressed and managed at a national level, and supported by modern legislative authorities.

2. Canada's approach to biosecurity for human pathogens and toxins is comprehensive and supported by national interventions that are proportionate to the unique risks found in each sector (e.g., academic, industry, hospital, public health, animal health). In Canada, biosecurity is considered to be a subcategory of good laboratory biosafety practices and acceptable levels of laboratory containment. Biosafety describes the containment principles, technologies, and operational practices that are implemented in order to prevent unintentional exposure to pathogens or toxins, or their accidental release.² In comparison, biosecurity refers to the security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of infectious material or toxins.³ These concepts are not mutually exclusive and are inherently complementary, as the implementation of good biosafety practices serves to strengthen biosecurity programmes, and vice versa.

Evolution of Canada's oversight for human pathogens and toxins: a stepwise approach

3. It has taken Canada many years to build its comprehensive oversight programme for managing risks posed by activities with human pathogens and toxins. Starting with voluntary guidelines, Canada systematically increased its oversight, and it is now supported by a modern legislative and regulatory framework, national standards, and a dedicated government agency responsible for administration and enforcement.

1990 Laboratory Biosafety Guidelines (national guidelines)

4. Canada's national oversight programme for biosafety and biosecurity began with the publication of the 1990 Laboratory Biosafety Guidelines. This was a voluntary national guidance document to promote the safe use and secure containment of human pathogens and toxins in laboratories.

1994 Human Pathogens Importation Regulations (controls for imported human pathogens)

5. In 1994, Canada established regulatory oversight for individuals seeking to import Risk Group 2, 3, or 4 human pathogens and toxins into the country. Import conditions set out under the 'Human Pathogens Importation Regulations' included mandatory compliance with the applicable sections of the Laboratory Biosafety Guidelines, supported by a national compliance and enforcement programme to promote, monitor, and verify compliance. Key compliance and enforcement activities included education and awareness of legal obligations, paper-based audits, and on-site inspections. The regulations also provided Canada with the authority to inspect laboratories before issuing an importation permit.

2009 Human Pathogens and Toxins Act (controls for domestically acquired human pathogens)

6. In 2009, Canada expanded its oversight to address risks posed by domestically acquired and/or domestically produced human pathogens and toxins, while maintaining oversight for imported human pathogens and toxins. The establishment of the new and modern Human Pathogens and Toxins Act allowed Canada to expand its national oversight, and to mitigate risks posed by

synthetically produced human pathogens, gain-of-function research, and research with dual-use capabilities.⁴ The establishment of new legal authorities also expanded Canada's national risk-based audit and inspection activities to promote and monitor compliance in all laboratories across Canada that conduct activities with human pathogens and toxins.

7. Certain parts of the Human Pathogens and Toxins Act were immediately brought into force as law in 2009 to strengthen biosafety and biosecurity in Canada. These included: modern inspection powers; relevant offence and penalty provisions; the mandatory registration of all laboratories in possession of human pathogens and toxins; a general duty of care to take all reasonable precautions to protect the health and safety of the public when knowingly dealing with these agents; a ban on any activity with smallpox; and a prohibition on intentionally releasing human pathogens and toxins causing risk to the health or safety of the public. The remaining sections of the Act required the support of a new programme and regulatory framework, that would include a licensing scheme and security clearance requirements.

2013 National Programme Harmonisation of Human and Terrestrial Animal Pathogens

8. To reduce the regulatory burden on stakeholders, Canada designated the Public Health Agency of Canada as the single national point of contact for laboratories working with human pathogens and/or terrestrial animal pathogens that are indigenous to Canada.⁵ Many laboratories in Canada work with both types of pathogens and, prior to the 2013 National Programme Harmonisation of Human and Terrestrial Animal Pathogens, stakeholders were required to contact two different government agencies to obtain permits to import human and indigenous terrestrial animal pathogens. The key outcomes of this initiative include less paperwork for regulated parties,

quicker turnaround times for import authorisations, streamlined national processes, system efficiencies, and strengthened oversight.

2013 National Harmonisation of Canadian Biosafety Standards and Guidelines

9. In 2013, Canada consolidated and updated older versions of laboratory standards and guidelines for human and animal pathogens to create the First Edition of the Canadian Biosafety Standards and Guidelines.⁶ The development of this document was supported by an external expert working group and extensive stakeholder consultation. The 2013 Canadian Biosafety Standards and Guidelines establishes risk and performance-based requirements for physical containment, operational practice, and performance and verification testing, in order to promote the safe handling and storing of human and indigenous terrestrial animal pathogens and toxins. They are Canada's national biosafety and biosecurity standard for laboratories working with these agents. Canada also created mobile phone and web applications for the 'Canadian Biosafety Standards and Guidelines', available as a free download.⁷

2015 Update of Canadian Biosafety Standards and Guidelines

10. A priority for Canada in 2014 and 2015 was an update to the standards and guidelines originally published as the First Edition of the Canadian Biosafety Standards and Guidelines. This update was necessary to align Canada's national standards of practice and laboratory containment with Canada's new regulatory requirements. These updates will be published as separate documents: the Canadian Biosafety Standard; the Canadian Biosafety Handbook; and a series of supporting Biosafety and Biosecurity Guidelines (for example, Canada is developing

best practice guidelines for developing facility biosecurity plans, working safely with Risk Group 1 human pathogens, and guidelines for veterinary practices).⁸

2015 Human Pathogens and Toxins Regulations

11. To support the full implementation of the Human Pathogens and Toxins Act, Canada approved the Human Pathogens and Toxins Regulations in 2015. The regulations support the implementation of a national licensing programme for Canadian laboratories working with human pathogens and toxins, and a security clearance programme for researchers and individuals with access to a list of high-consequence human pathogens and toxins (known as “security sensitive biological agents” in Canada). The new regulations also outline the functions to be performed by a designated Biological Safety Officer at a licensed organisation, and provide some exemptions from licensing for sectors that conduct low-risk activities with human pathogens or toxins.

12. On December 1, 2015, the Human Pathogens and Toxins Regulations came into force, along with the remaining provisions in the Human Pathogens and Toxins Act. Compliance with the requirements set out in the Canadian Biosafety Standard will be mandatory for all licensed organisations, and persons with access to security sensitive biological agents will require a security clearance, as specified in the Human Pathogens and Toxins Act.

Working together to mitigate risks: Canada’s whole of government approach

13. There are a number of agencies in Canada that work together to facilitate a whole of government approach to pathogen biosafety and biosecurity.

14. The Public Health Agency of Canada is Canada's national authority for the biosafety, containment, and biosecurity of human and terrestrial animal pathogens and listed microbiological toxins. The Public Health Agency of Canada relies on key partners to support national programme implementation.

15. The Canadian Food Inspection Agency is responsible for the co-development and maintenance of the national standards and supporting guidelines for human and terrestrial animal pathogens and toxins.⁹ In collaboration with the Public Health Agency of Canada, it conducts joint inspections and delivers biosafety training resources. It is also the national authority for the biosafety and biosecurity of animal pathogens causing Foreign Animal Diseases, emerging animal pathogens, as well as plant and aquatic pathogens. This authority supports the issuance of import permits and permit conditions.

16. The Canada Border Services Agency is Canada's national authority for border protection and control.¹⁰ It provides administrative support at Canadian points of entry for imported pathogens, supported by an electronic pre-clearance system that verifies importation authorisation, given by either the Public Health Agency of Canada or the Canadian Food Inspection Agency.

17. Global Affairs Canada (formerly the Department of Foreign Affairs, Trade, and Development) is Canada's national authority for issuing export and import permits for toxicological and biological agents on Canada's national Export Control List.¹¹ They also lead

Canada's involvement in the Biological and Toxin Weapons Convention, United Nations Security Council Resolution 1540, and the Global Partnership Programme.

18. Transport Canada is the national authority in Canada for regulating the transportation of dangerous goods, including high-risk pathogens.¹² They are responsible for shipping and transportation controls for pathogens and toxins, as per the 'Transportation of Dangerous Goods Act' and regulations.

19. The Royal Canadian Mounted Police provide support to compliance and enforcement, if required (for example, investigations, seizure and detention of pathogens or toxins), and in matters that impact national security.¹³ They also support the Human Pathogens and Toxins Act security clearance programme, by providing data record checks as specified in the regulations.

20. The Canadian Security Intelligence Service conducts and provides national oversight programmes with threat and risk assessment reports, which inform evidence and risk-based decision-making.¹⁴ It also supports the Human Pathogens and Toxins Act security clearance programme by providing data record checks, as specified in the regulations.

21. In addition to the many government departments that cooperate to support national biosafety and biosecurity, there are a number of stakeholders that work closely with the Public Health Agency of Canada:

- i. Licence Holders under the Human Pathogens and Toxins Act are responsible for ensuring compliance with biosafety and biosecurity requirements set out in the legislation, regulations, Canadian Biosafety Standard and other licence conditions.
- ii. Biological Safety Officers are designated by the licence holder under the Human Pathogens and Toxins Act. Their primary responsibilities are to promote and monitor compliance on behalf of the licence holder, to be the main point of contact with the Public Health Agency of Canada, and to carry out the functions set out in the regulations.
- iii. Persons authorised to work under a licence are also responsible for complying with the requirements set out in the legislation, regulations, Canadian Biosafety Standard and other licence conditions.

Promoting a culture of shared understanding and responsibility

22. Canada is committed to helping build national capacity and a network of trusted partners. There are a number of working groups across the Canadian Government and engagement activities with the pathogen user community to support and strengthen biosafety and biosecurity best practices in Canada, and to ensure a common understanding of why biosafety and biosecurity is important.

Canadian Pathogen Security Partners Working Group

23. For example, the Canadian Pathogen Security Partners Working Group was established in 2012 to build and strengthen relationships between Canadian government departments responsible for the oversight and risk management of pathogens and toxins in Canada. The mandate of this working group is to: enhance pathogen security in Canada using a coordinated, whole of government approach; increase communication and collaboration between government departments; increase biosecurity awareness, with a specific focus on the academic community; and share lessons learned from implementing national regulatory programmes and other risk mitigation measures. This working group supports national programme implementation and bridges gaps between public health, law enforcement, and intelligence communities. Similarly, Canada established the Canadian Pathogens Partners Working Group in 2012, to help streamline national oversight systems and regulatory authorisation processes. The aim of this working group is to reduce barriers faced by the pathogen user community, and to resolve regulatory challenges.

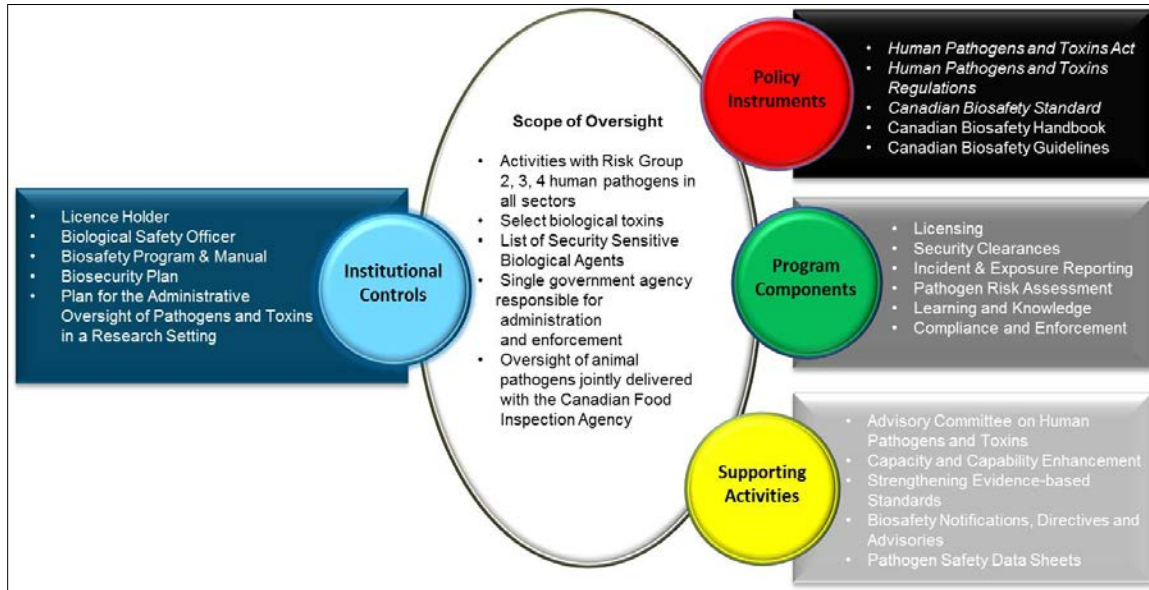
Prioritising stakeholder engagement

24. Canada is committed to working closely with its stakeholders to inform the development of various policy instruments and implementation tools. For example, to inform the development of the Human Pathogens and Toxins Regulations, Canada designed and implemented a multi-year consultation strategy.¹⁵ The overall strategy for the Human Pathogens and Toxins Regulations was developed following a pre-consultation (Phase 1) with provincial and territorial government departments and key national associations. Phase 2 of the strategy included a consultation on key

national programme elements such as licensing, the functions and qualifications of Biological Safety Officers, inventory requirements, reporting of laboratory-acquired infections, and security clearance requirements. Phase 3 was designed to seek stakeholder input regarding the government's proposed policy approaches to these same issues, and to identify any potential operational challenges to implementation. Finally, Phase 4 involved the publication of the Government's proposed regulations for public comment, and was complemented by information sessions for the various regulated sectors and pathogen users in Canada.

25. The feedback received through consultations and other engagement activities provided valuable input that informed the development of the national programme and regulatory framework for human pathogens and toxins, as reflected in Box 17.1. The development of this comprehensive oversight framework took many years, starting in 2009, and ending in 2015, with Canada's approval of the Human Pathogens and Toxins Regulations; development will continue with regular reviews of regulatory effectiveness and impact.

Box 17.1: Canada’s national programme and regulatory framework for human pathogens and toxins.



26. In addition to prioritising stakeholder engagement and consultation, Canada is dedicated to providing support to regulated parties to help them achieve compliance with biosafety and biosecurity requirements. For example, the Public Health Agency of Canada agreed to take part in a research project with McGill University at the outset of the regulatory development process. This project aims to better understand behavioural indicators and their impact on regulatory compliance. Early lessons learned informed the development of the national programme and regulatory framework for human pathogens and toxins in Canada, including the careful selection and mix of policy instruments, and the development of various implementation tools and resources to help strengthen compliance rates.

Increasing the understanding of biosecurity through targeted outreach and education

27. There is recognition in Canada that scientific research with human pathogens and toxins poses a higher degree of risk to the safety and security of the public. Many of the characteristics of a successful research environment – such as experimentation, innovation, a culture of academic freedom, international collaborations and the need to publish—are in conflict with health security objectives found in regulatory oversight regimes.

28. To address this tension between the need for innovation and regulatory oversight, the Public Health Agency of Canada actively engaged the research community. This included a series of exploratory meetings with universities across the country, which united the academic community with Canada's public health, security, and intelligence partners. The purpose of this initiative was to discuss how best to raise awareness of the inherent biosecurity risks associated with research, such as dual-use capabilities, intangible technology transfer, material acquisition and proliferation, and insider threats, and to discuss practical ways to mitigate these risks. The input collected will inform a proposal to pilot a formal outreach initiative.

29. In addition, the Agency met individually with senior administrators from small, medium, and large universities to discuss how best to mitigate biological risks from an organisational perspective. Discussion themes included governance and administrative oversight systems, risk management practices, reporting structures, integration of safety committees and training, and internal biosecurity policies and procedures.

30. The Agency also supported the formation of a Canadian Academic Biological Safety Officer's Network, to allow for the building of a community of practice and the sharing of best practices across the country.

31. Lastly, the Agency became involved in the International Genetically Engineered Machine (iGEM) Competition, to instil good laboratory biosafety and biosecurity and risk management practices. Established in 2004, the iGEM Competition is the premier student competition in the new field of synthetic biology (see Chapter 4 and 12).¹⁶

Understanding sector risks and strengthening institutional accountability

32. It is important for national authorities to understand the type of activities being conducted with pathogens across the country within each sector, and the risks posed by those activities, along with the supporting behaviours at an individual and organisational level.

33. When designing Canada's national oversight framework for the biosafety and biosecurity of human pathogens and toxins, the Public Health Agency of Canada considered the unique characteristics of the research environment. As previously stated, these characteristics often create tension between the need for government intervention to protect the health and safety of the public, and the need for unconstrained oversight to safeguard scientific freedom and innovation.

34. The research sector faces additional risks that other sectors (e.g., diagnostic and private industry) normally do not. These factors include, but are not limited to: conducting research with

dual-use capabilities and gain-of-function outcomes; autonomous research and researchers; diffused accountabilities; and complex reporting and governance structures.

35. If a licence applicant in Canada is conducting scientific research, as defined in the Human Pathogens and Toxins Regulations, they are required to submit a plan for the administrative oversight and management of research risks in their organisation (Plan for Administrative Oversight). This policy tool is sector-specific, and was designed to increase awareness of the need to identify and manage biological risks at an organisational level, and to encourage low level actors to be responsible for organisational outcomes. This means of creating responsiveness, responsibility and consequences for non-compliant practices in laboratories should help bridge the gap between national framework expectations and compliance performance.

36. The Plan for Administrative Oversight is intended to be a high level document, which provides an overview of the mechanisms in place to administratively manage and control biosafety and biosecurity risks. Box 17.2 describes the elements required in Canada for submitting a Plan for Administrative Oversight.

Box 17.2: Elements of a plan for administrative oversight.

- I. Commitment from Senior Management to manage and control biosafety and biosecurity risks at the institution/organisation.
- II. Delineation of the roles and responsibilities for committees, individuals, and departments that have a role in the control/management of biosafety and biosecurity risks.
- III. Establishment of a single point of contact to provide guidance on the Plan, and a senior level 'champion' who can represent biosafety issues at a senior level on his/her behalf.
- IV. Overview of how biosafety and biosecurity risks, including those from dual-use research, are identified at the institution/organisation.
- V. Overview of how biosafety and biosecurity risks, including those from dual-use research, are assessed once they have been identified at an institutional/ organizational level.
- VI. Overview of how the biosafety and biosecurity risks are managed and controlled at an institutional/organisational level, including those from dual-use research.
- VII. Description of all work areas covered by the Plan (research areas, teaching, off-site etc.).
- VIII. Description of all individuals covered by the Plan (researchers, faculty, students etc.).
- IX. Summary of how the Plan is communicated.
- X. Overview of the procedures to review and monitor the Plan.

Key elements of Canada's biosecurity programme

37. Canada's biosecurity programme for human pathogens and toxins is designed to prevent loss, theft, misuse, diversion, or intentional release of human pathogens and toxins – including the release of other regulated infectious material and facility assets (e.g. non-infectious material, animals, sensitive information). The national programme is supported by new and modern authorities, established under the Human Pathogens and Toxins Act and supporting Human Pathogens and Toxins Regulations, and is comprised of the following key elements.

Facility licensing

38. All persons that conduct controlled activities in Canada with human pathogens or toxins (i.e. possessing, handling, using, producing, storing, permitting access to, transferring, importing,

exporting, releasing, abandoning, or disposing) are required to obtain a licence from the Public Health Agency of Canada. This mandatory requirement will allow for the identification and location of human pathogens and toxins in Canada, including the most dangerous pathogens, and will replace the 2009 laboratory registration scheme. In practice, the organisation where activities are taking place will apply for a licence, to ensure that all people and laboratories under its purview are authorised to handle and store these agents. Separate licences will be required for organisations that conduct controlled activities with Risk Group 2 human pathogens, Risk Group 3 human pathogens, Risk Group 4 human pathogens, and for toxins that are listed in Schedule 1 of the Human Pathogens and Toxins Act.¹⁷

Role for Biological Safety Officers

39. Before a licence can be issued by the Public Health Agency of Canada, a licence applicant is required to designate a Biological Safety Officer. The Biological Safety Officer will be the main point of contact between the licensed organisation and the Agency, and a key compliance and monitoring resource for the licence holder. Minimum qualifications and mandatory functions for a designated Biological Safety Officer are set out in the Human Pathogens and Toxins Regulations. Some examples of the functions include: organising biosafety and biosecurity training; conducting laboratory inspections and biosafety audits; informing the licence holder in writing of any issues of unresolved non-compliance; and assisting with internal investigations for laboratory incidents.

Security clearances

40. In Canada, individuals that work with, or have access to, security sensitive biological agents (a list of prescribed Risk Group 3 and 4 human pathogens, and select micro-biological toxins in specified quantities) are required to obtain a security clearance from the Public Health Agency of Canada. This includes individuals conducting research, those who require access to storage space, workers or researchers that open shipments containing security sensitive biological agents, and personnel that handle or care for animals experimentally infected. The security clearance requirement set out under the Human Pathogen and Toxins Act supports personnel suitability and ongoing reliability, which are required elements of a biosecurity plan in Canada. This security clearance requirement also helps to reduce risks associated with personnel, such as insider threats. This is achieved through a security risk assessment that includes database checks conducted by Canadian law enforcement and intelligence partners, as well as a credit check. The security clearance application process includes the submission of finger prints and a signed statement from the licence holder, certifying that access to these agents is needed.

Incident reporting

41. A licence holder in Canada has a legal obligation to inform the Public Health Agency of Canada if any of the following incidents with human pathogens and/or toxins occur: inadvertent release from a laboratory; inadvertent production of a human pathogen or toxin; an incident that has or may have caused a disease; and stolen or otherwise missing human pathogens or toxins. In addition, there are regulatory requirements to inform the Agency when: a prescribed security sensitive biological agent is lost in transit for more than 24 hours; when there is a name change related to the licence holder; and when a licence holder makes a decision to prohibit the holder of

a security clearance from having access to the organisation to which the licence applies. There is also a requirement in Canada to notify the Agency before any changes are made to physical structures, equipment, or standard operating procedures, that could affect the laboratory containment of Risk Group 3 or 4 human pathogens or prescribed security sensitive biological agents.

Biosafety programme and manual for licensed organisations

42. In Canada, a licensed organisation is required to have a biosafety programme in place that is supported by a Biosafety Manual that will document the programme and describe how the organisation will achieve the goals and objectives of the programme. This Manual must be kept up to date and integrated with key components in the organisation's Plan for Administrative Oversight. Common safety measures in a biosafety programme include good microbiological laboratory practices, appropriate primary containment equipment, and proper physical design of the containment zone. Organisations implementing biosafety programmes must ensure that they are in compliance with the Canadian Biosafety Standard. As mentioned earlier in this Chapter, the Canadian Biosafety Standard is Canada's updated national standard for the safe use and secure laboratory containment of human and terrestrial animal pathogens and toxins. Core elements of a biosafety programme include a comprehensive training programme, medical surveillance programme, emergency response plan, Standard Operating Procedures that follow safe work practices, and a Biosecurity Plan.

Biosecurity plan for licensed organisations

43. All licensed organisations in Canada are required to develop, implement, monitor and review a Biosecurity Plan that describes mitigation strategies for the risk associated with biological assets (i.e. human pathogens and toxins) in a facility's possession. A Biosecurity Plan (Box 17.3) must cover five areas: physical security; personnel suitability and reliability; pathogen and toxin accountability and inventory control; incident and emergency response; and information security. An effective Biosecurity Plan is developed, based on a site-specific assessment of the biosecurity risks in an organisation, and should be incorporated into existing security protocols (e.g. emergency response protocols). Integrating the elements of a Biosecurity Plan within an overarching biosafety programme will minimise duplication of information, and allow for a more efficient biosafety management system.

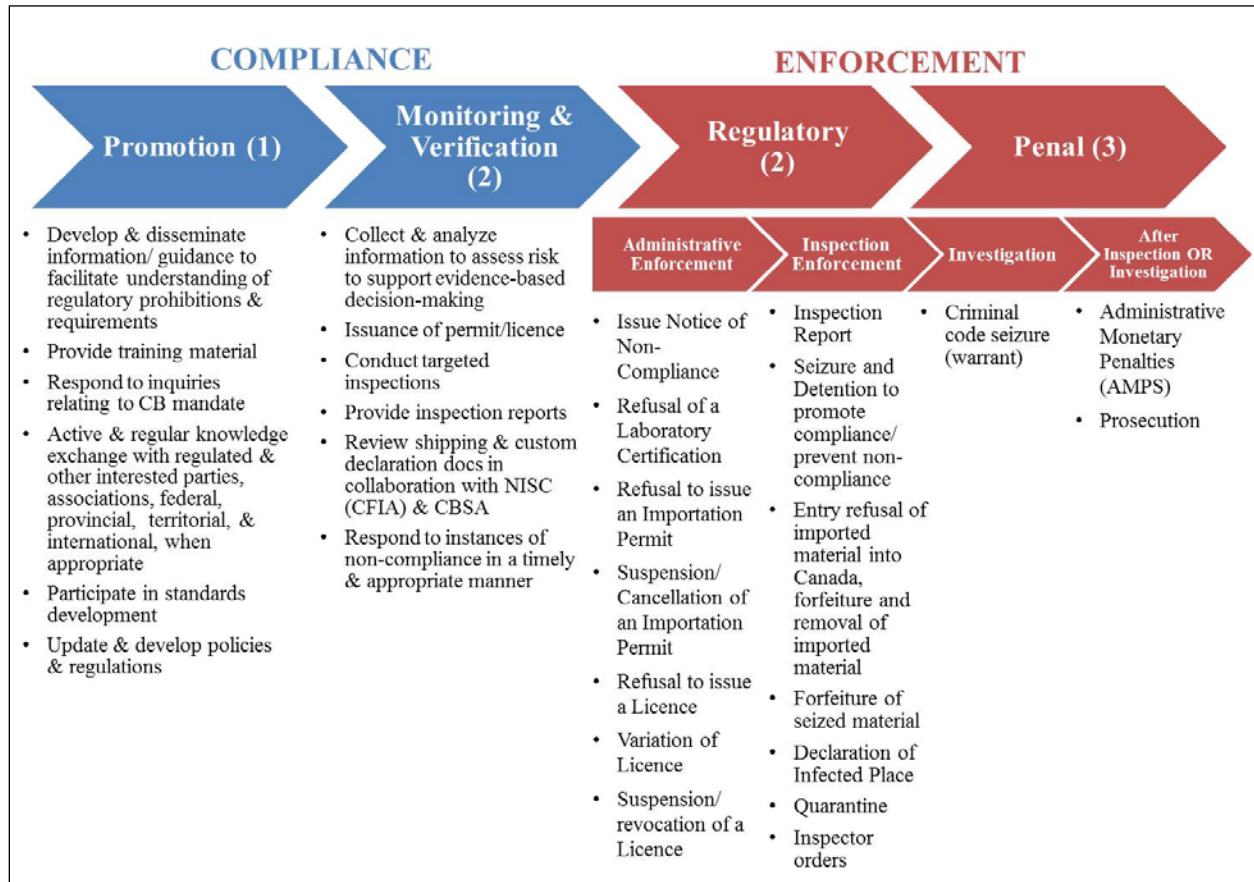
Box 17.3: The five pillars of a biosecurity plan in Canada.

- | |
|--|
| I. Physical Security |
| II. Personnel Suitability and Reliability |
| III. Materiel Control and Accountability (Inventory) |
| IV. Incident and Emergency Response |
| V. Information Security |

National compliance verification programme

44. Canada's approach to biosafety and biosecurity includes a national compliance and enforcement programme.¹⁸ Canada uses different tools and strategies to promote, monitor, and verify compliance, including the delivery of training and educational resources, and conducting audits and inspections. Box 17.4 summarises Canada's compliance and enforcement activities in a continuum.

Box 17.4: Canada’s compliance activities and enforcement continuum.



Ongoing challenges for Canada

Risk assessment of novel/emerging pathogens

45. A novel or emerging pathogen is one that presents a new or recent threat to human health; it may result from the evolution or change of an existing microorganism, from the spread of a microorganism to a new geographical area or population, or it may simply be a newly identified pathogenic agent. Canada has developed a robust risk assessment framework, through which novel and emerging pathogens are currently assessed. The objective of conducting a risk assessment is to determine the appropriate Risk Group classification and biosafety containment

requirements for work with a given pathogen. It includes three overarching components: hazard identification; hazard characterisation; and exposure assessment.

46. However, a challenge that often exists, when evaluating the risks posed by a novel or emerging pathogen, is the lack of sound scientific data to support the analyses. When data is incomplete or not available, assumptions are made to facilitate the decision making process. These include the consideration of surrogate data, such as known pathogenicity (e.g., known for animal health but not for human health, or known for genetically related pathogens) and the likelihood of exposure. Novel and emerging pathogens are continuously monitored and, when new information becomes available, pathogen risk assessments are updated accordingly.

47. In addition to the risk assessment methodologies in place, Canada has also convened an Advisory Committee on Human Pathogens and Toxins, comprised of scientific experts who will provide advice on domestic biosafety risks. This will include the assessment of novel and emerging pathogens, as needed, and recommendations on their Risk Group classification and biosafety containment requirements.

Preventing and managing risks posed by emerging science and research with dual use capabilities

48. Canada has established an oversight mechanism for dual-use activities, by requiring laboratories that conduct scientific research to submit a Plan for Administrative Oversight (see paragraphs 35, 36). The Plan will explain how their laboratory administratively manages and controls biosafety and biosecurity risks, including potential risks from dual-use research

(includes gain-of-function). Dual-use research refers to the knowledge, tools, technology, and products generated by legitimate life sciences research that have the potential to be misused or misapplied for malicious purposes, and could be detrimental to public health and safety, the environment, or national security.

49. The Plan includes guidance that will enable a proper assessment of the potential risks, and the development of risk mitigation and monitoring plans related to known dual-use activity or potential misuse of research information (e.g., data, methodology), technology, and/or intermediate and final products (e.g., pathogen or toxin).

50. Individuals are also required under Canada's regulations to notify their licence holder and Biological Safety Officer before there is an intentional modification to a human pathogen that could increase its virulence, pathogenicity or communicability. The notification also applies to any intent to increase the resistance of a human pathogen to preventative or therapeutic treatments, or to increase the toxicity of a toxin.

Keeping pace with scientific advancements and developing foresight

51. Canada recognises that the rapid growth of emerging life science technologies and the convergence of several academic disciplines will change the way that government addresses risks and regulates stakeholders. In the future, the Public Health Agency of Canada will require a science capacity within the organisation, to provide risk assessors and front-line inspectors with the necessary knowledge, tools, techniques, and training related to new scientific developments.

52. The Agency will build on its strengths as an open, inclusive, and collaborative organisation to engage unconventional stakeholders, such as citizen scientists, do-it-yourself communities, chemists, physicists, engineers, software developers, computer programmers, and more. By promoting and supporting sustainable cross-disciplinary networks with domestic and international experts, Canada will be able to facilitate the rapid exchange of scientific knowledge, skills, and expertise to keep pace with scientific advancements.

Practical steps towards developing national oversight frameworks for pathogen biosafety and biosecurity

53. The following steps provide an analytical framework to guide the development or modernisation of national oversight and accountability systems for pathogen biosafety and biosecurity. This basic structured process incorporates a whole-of-government approach to managing the risks and core policy issues to be considered and discussed. It is intended for use by public service employees who are working in government departments involved in the development of national or regional programmes or supporting their implementation.

54. A key benefit of this framework is that it can be used to gain political support to address biosafety and biosecurity risks, because it provides a process for shaping a narrative that can be used to brief Ministers and senior officials. It can be also used to drive work forward, if there is already political support.

55. Key steps in the analytical framework are working in collaboration with the pathogen user community to understand a country's unique risk environment, and evaluating the range of instruments available to government to achieve desired safety and security policy objectives.

Box 17.5: Practical steps to developing or modernising national frameworks for biosafety and biosecurity.

I. Define the problem/risks to public health, safety and security

Examples

- ✓ Accidental release of a pathogen from a lab
- ✓ Deliberate release of a pathogen from a lab
- ✓ Theft or missing pathogens, material, equipment
- ✓ Pathogen exposures
- ✓ Research with dual use capabilities
- ✓ Gain of function research
- ✓ Transfer of intangible technology
- ✓ Emerging technology

II. Identify and assess what is contributing to the problem/risk

Examples

- ✓ Unsustainable or inadequate laboratory containment standards?
- ✓ Lack of standard operating procedures?
- ✓ Lack of biosafety training?
- ✓ No inventory system?

- ✓ Limited biosafety and biosecurity expertise?
- ✓ Outdated or unattainable standards of practice?
- ✓ Limited or dated legal authorities?
- ✓ Limited or no compliance and enforcement capacity?

III. Identify and assess who is contributing to the problem/risk (understand who is conducting activities with pathogens in your country and what's going on within each sector and why)

Examples

- ✓ Academia (institution, students, researchers, principal investigators)
- ✓ Industry (biotechnology, synthetic biology)
- ✓ Diagnostic
- ✓ Hospitals (academic affiliated and non-affiliated)
- ✓ Public Health
- ✓ Distributors
- ✓ Animal Health/Veterinary
- ✓ Environment

IV. Identify and assess critical intervention points that can help reduce risk (are there opportunities/limitations/gaps linked to specific activities?)

Examples

- ✓ Possession, handling and storage
- ✓ Production
- ✓ Importation, exportation and transfer activities
- ✓ Transportation

- ✓ Permitting persons access to pathogens
- ✓ Physical structures
- ✓ Recruitment of researchers
- ✓ Distribution chain

V. Identify and assess the various policy instruments/tools that may help to reduce risk

Examples

- ✓ Voluntary Measures
- ✓ Legislation
- ✓ Regulations
- ✓ Training
- ✓ Advisories
- ✓ Guidelines
- ✓ Standards
- ✓ Licensing
- ✓ Security Clearances
- ✓ Reporting of incidents (e.g., exposure, accidental release)

VI. Select the appropriate mix of government instruments to address the problem/risks

Considerations

- ✓ What will be the most effective tool or mix of tools to affect a positive change in behaviour?
- ✓ Do you have (or want) legal authorities to require people to follow a common set of rules?

- ✓ Do you have existing authorities to intervene if there is a risk to public health and safety? Do you have the resources, capacity and ability?

VII. Develop a road map or strategic plan to get you where you need to be

Considerations

- ✓ Rome wasn't built in a day; it will take years to build and implement a comprehensive oversight framework
- ✓ Decide what you want to focus on first; plan using a stepwise approach
- ✓ Do you have the people and resources to support concurrent activities/actions, or do you need to plan for a sequencing of activities?
- ✓ Leverage support, expertise, resources, relationships and partnerships to help you get there
- ✓ Engage stakeholders in the development of your solutions (engage early and often)
- ✓ Is there a specific sector or group of stakeholders that may benefit from targeted engagement, due to their unique challenges in upholding good laboratory biosafety and biosecurity practices?

VIII. Set your guiding principles, public policy objectives and expected outcomes

Examples

- ✓ National oversight framework will be designed to:
 - facilitate the best and most innovative science in a manner that is safe and secure
 - enable public health labs to respond to disease outbreaks as efficiently as possible, in a manner that is safe and secure
 - help keep pathogens and the public safe, while maintaining a competitive edge for businesses and the economy as a whole

- ✓ Policy objectives:
 - protect the health and safety of the public from risks posed by a range of activities involving human and animal pathogens and toxins
 - identify and risk manage the most dangerous pathogens in the country
 - early detection of biological threats
 - prevent the proliferation of biological weapons
 - rapid response to incidents involving pathogens
 - promote the same standards of practice and containment
 - prevent laboratory exposures and other incidents
 - strengthen regulatory alignment with other international partners
- ✓ Expected outcomes:
 - increased awareness of biosafety and biosecurity and supporting requirements
 - safe use and secure containment of pathogens used in labs across the country
 - dangerous pathogens are identified, held, secured and monitored in a minimal number of laboratories according to best practices
 - single government agency in place to administer and enforce
 - reduced incidents including laboratory exposures, accidental and deliberate releases
 - increased monitoring and reporting of incidents

IX. Design and develop your policy instruments/tools

Considerations

- ✓ Go back to your strategic plan; what will you focus on first?
- ✓ Do you have the resources and expertise or do you need assistance?

- ✓ What are your plans for engaging and/or consulting the pathogen user community and other stakeholders?
- ✓ There may be an opportunity to adopt and adapt another country's policy tools, such as biosafety training resources developed and in use by another country
- ✓ There may be an opportunity to design stand-alone legislation versus legislation designed to be supported by regulations
- ✓ You can legally require stakeholders to follow a set of common biosafety, biocontainment and biosecurity standards, by referencing the standard directly in the legislation, or by making it a condition of a licence or laboratory registration

X. Set your performance indicators

Considerations and Examples

- ✓ Need to plan for the assessment of your government interventions and policy tools, to see if they are meeting your intended public health, safety and security objectives
- ✓ Examples of indicators
 - Percentage of those receiving biosafety training who are satisfied with the training
 - Number of licences issued within the established service standard (e.g., 20 days)
 - Number of laboratory acquired infections
 - Number of laboratories in country that are registered
 - Number of laboratories in country that are in compliance with biosafety and biosecurity standard

XI. Plan for implementation

Considerations

- ✓ What resources and tools are needed to support implementation? (e.g., fact sheets, guidance documents, training, SOPs, videos, apps, etc...)
- ✓ What needs to be published online for stakeholders?
- ✓ Establish service standards, if applicable (e.g., licensing or security clearance programme, audit or inspection programme)
- ✓ Do you need implementation support from another department or agency?
- ✓ Giving stakeholders and national supporting programmes time to prepare for implementation may be beneficial (e.g., could be achieved by delaying the coming into force date of the approved law or regulation)
- ✓ What is your approach to, and plan for, compliance and enforcement?(e.g., compliance promotion, compliance monitoring, enforcement)

XII. Implement national framework for biosafety and biosecurity

Considerations

- ✓ Measure and report on performance
- ✓ Evaluate supporting national programmes (e.g., licensing, security clearance, inspection)
- ✓ Lifecycle management and review of existing policy tools including legislation, regulation, and national standards
- ✓ What's working? What needs to be adjusted?

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Chapter 18: Future governance of biotechnology

Catherine Rhodes

Key learning objectives

- i. Understand how international rules are important for all activities in the life sciences.
- ii. Show the routes through which scientists can influence the development and implementation of these international rules.
- iii. Explain the contributions scientists can make as individuals to strengthening/enhancing such processes.

Introduction

1. While international policy can seem remote from individual activities, the rules and standards developed at the international level influence activities in the life sciences, and how science and technology are directed and applied. International governance can also influence who participates in and benefits from scientific and technological advances. Even some routine procedures (such as those for basic laboratory biosafety) have strong connections to international standards.

2. This chapter covers the international governance of biotechnology – picking up on several of the regulations mentioned in Chapter 7 – but focusing on the impacts that international governance can have on scientists and how they, in turn, can play a role in its future development and implementation – for example by promoting use of scientific evidence in international policy-making.

What is international governance?

3. There are some issues which states decide need to be managed internationally in a harmonised way. These are generally issues that have cross-border impacts, and/or cannot be effectively addressed by individual states taking separate actions – climate change is an obvious example. Scientific work often has strong international dimensions – e.g. through multi-national collaborations, and dissemination of findings through international conferences and journals. Scientific knowledge and expertise easily moves across national borders. Technological innovations – which are now more closely linked to the pace of scientific advance – also spread rapidly through international trade. Various aspects of scientific activity, its applications and impacts are therefore now addressed through international governance.

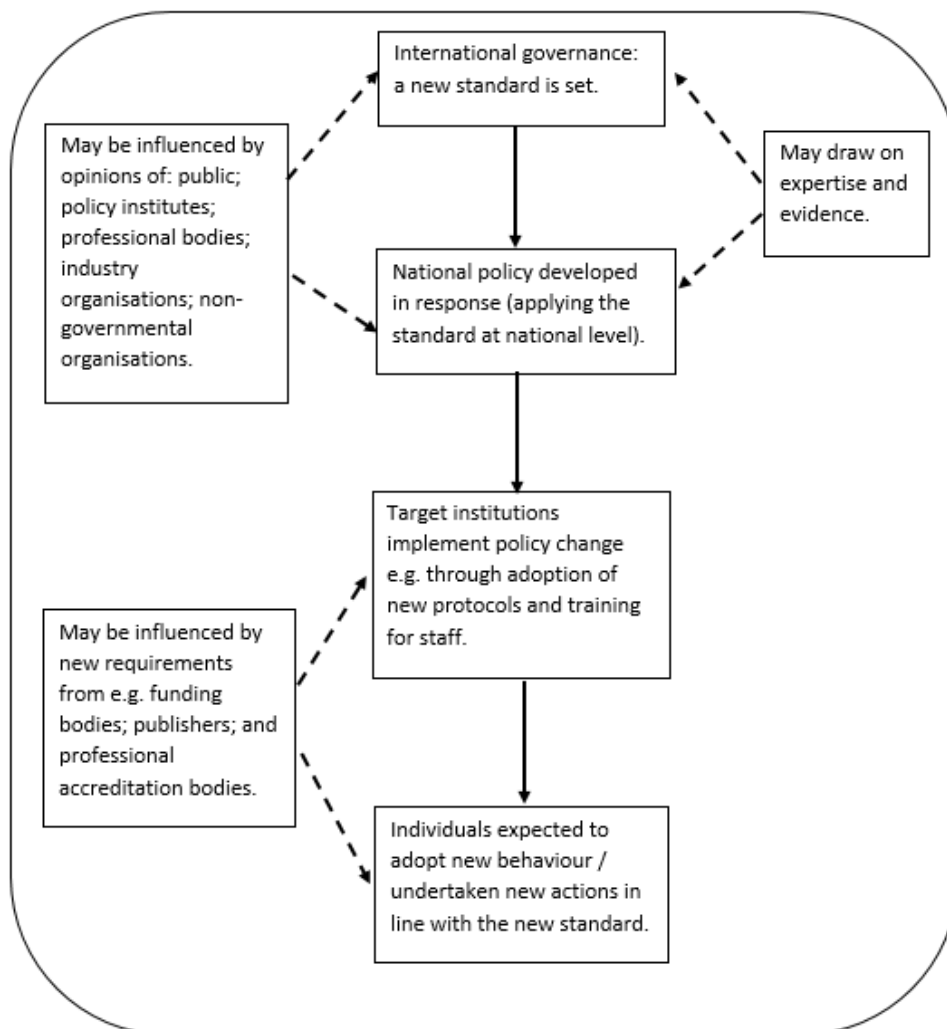
4. Once it is decided that an issue should be governed internationally, states will generally negotiate an agreement outlining how the issue should be addressed. This can be done in a legally-binding manner – usually through treaties or conventions – or through creation of standards, guidelines and codes, with which compliance is voluntary. Voluntary rules do not necessarily have less influence on states' behaviour, and they can have some advantages in the governance of science, because they can be more rapidly updated in line with scientific advances. States that subscribe to a particular treaty or convention are referred to as its 'States Parties'.

5. States have established many international organisations to facilitate negotiation of such agreements, and to support their implementation (for example, the World Health Organization or the Food and Agriculture Organization). International organisations generally: have a secretariat responsible for day-to-day administrative and oversight activities, headed by an 'executive secretary' or 'director-general'; a governing body made up of member state representatives, which has decision-making powers; and subsidiary bodies such as committees, advisory boards and expert groups, which support the organisation by addressing particular matters in more depth, and which may be permanent or ad hoc in nature.

6. International organisations often develop other mechanisms to support their work. These include: reporting mechanisms; monitoring and surveillance networks; assessments and reports on particular issues (including scientific and technological assessments); and convening of expert networks.

7. Awareness of this general structure of international governance (Figure 18.1) will aid understanding of routes through which scientific expertise can influence the development and implementation of international rules – particular examples are provided later in this chapter.

Figure 18.1: From international governance to individual action.



How does international governance affect science / individual scientists?

8. This section starts with general points – specific examples relevant to biotechnology are provided later.

9. International rules rarely have direct effects on individuals. Domestic policy and/or legislative changes are usually necessary for national implementation – adoption of relevant national implementing measures is frequently a requirement in international rules. There is often scope left in the wording of international rules for some flexibility in interpretation and selection of implementation methods. Not all countries will implement rules in exactly the same way, but there is an expectation of a minimum level of compatibility. Countries are often required to report to the relevant international organisation on the national implementation measures they have adopted. This helps to provide transparency, and may also encourage others to do likewise, and to share best practice.

10. There will usually be at least one intermediate level between national policy and individual scientists. This will often be the employing institution – or, for students, the host university – but it may also have effect through funding bodies, professional associations, academies, or publishers.

11. For example, in relation to biosecurity, in response to revised national policy guidance:

- i. The institution may set e.g. access controls on particular materials;
- ii. Funding bodies may require review of biosecurity implications as part of grant applications. For example, in the United Kingdom, the Wellcome Trust, the Biotechnology and Biological Sciences Research Council, and the Medical Research Council ask their reviewers and applicants to consider risks of misuse associated with their applications;¹
- iii. Scientific academies may adopt codes of conduct or policy statements to advise their members. An example of this is the 2005 Statement on

Biosecurity of the InterAcademy Panel on International Issues (see Chapter 10);²

- iv. Publishers may review the biosecurity implications of publishing certain research findings in full. An example of how this has been handled in practice can be found in Chapter 2.

12. There may also be specific roles for local agencies (police, or health and safety groups, for example) to support, monitor and enforce compliance. Good working relationships between laboratory facilities, local law enforcement agencies and emergency responders are, for example, encouraged in the World Health Organization's Laboratory Biosecurity Guidance³.

13. Individuals will then be expected to modify their activities or behaviour, in order to comply with institutional and other requirements.

Impacts of international governance on the practice, direction and application of science

14. One target for international governance can be change to scientific practice or procedures; it can also influence scientists by promoting particular research and applications, and limiting or prohibiting others. It can also create procedures by which individual states can assess and choose to ban certain innovations from their territory. It is important to be aware that the role of governance is not exclusively about constraining or restricting scientific work; it can also promote and facilitate it. For example:

- i. The Cartagena Protocol on Biosafety sets out procedures through which States must give advance informed agreement to the first transboundary movement of any particular living modified organism into their territory⁴;
- ii. The Codex Guidelines, relating to safety assessment of foods produced using / derived from modern biotechnology, advise against use of antibiotic resistance marker genes that may remain present in food products⁵;

iii. The Convention on Biodiversity promotes uses of modern biotechnology to support its goals of conservation of biodiversity and sustainable use of its components, including transfer of knowledge and technology to developing states⁶.

15. This means that individual scientists may find that they are actively encouraged to pursue particular areas of research in line with global priorities, or that there are limits to how their research may be applied.

16. International governance can more broadly influence the direction of scientific work (either deliberately or as an unintended side-effect); again, this can be through the promotion of particular priority goals for global research efforts (e.g. targeting a particular disease threat); or through more indirect impacts, such as establishment of international minimum standards for intellectual property protection, thus encouraging more commercially-oriented innovation.

17. International governance can also facilitate broader participation in research, by promoting scientific and technological capacity-building for developing countries. International organisations help with the development and implementation of training e.g. for appropriate standard-setting, through the Standards and Trade Development Facility. Explicit recommendations on capacity-building, knowledge exchange and technology transfer are contained within many of the international rules relevant to biotechnology. Individual scientists can play an active role in capacity-building activities, e.g. through participation in international collaborative projects.

Which elements of international governance of biotechnology are of particular relevance to scientific activities?

18. As noted in Chapter 7, biosecurity governance is not only contained within the Biological and Toxin Weapons Convention; there are a range of other international rules and processes that play an important contributory role. Many of these were identified in Chapter 7. This current chapter focuses on explaining how these rules

can impact scientific activities, and how scientists can have input into their development and implementation.

19. When looking at international governance, it can be difficult to identify all the rules and organisations relevant to biotechnology. Not all of the relevant rules will explicitly mention biotechnology, particularly within their titles. A good starting point for identifying relevant rules and organisations is to identify the areas in which biotechnology activities and their applications are likely to have impacts (including beneficial as well as potentially negative impacts)⁷. For biotechnology in general, there are nearly forty applicable international regulations, and at least fifteen international organisations with an interest in the area. Rather than cover them all, this chapter focuses on a selection of particular relevance to biosecurity aspects of life sciences research.

The Biological and Toxin Weapons Convention and the Chemical Weapons Convention

20. Chapter 7 provides more details about the provisions of these Conventions. In regard to their impacts on scientific activities, they clearly prohibit any work which develops, produces or uses biological agents and toxins for non-peaceful purposes; they also promote work involving biological agents and toxins for peaceful purposes, and encourage technology transfer and scientific assistance for such purposes. In promoting measures to support implementation of the Conventions, meetings of States Parties (e.g. at their Review Conferences and annual meetings within the BTWC inter-sessional process) have addressed the scientific community with recommendations including development of ethics education, training and codes of conduct. These may be understood as attempts to change scientific culture and, through that, to influence practice. Kuhlau *et al.* provide an explanation of educational elements needed to promote a culture of responsibility in their 2012 paper Ethical Competence in Dual Use Life Sciences Research⁸:

A culture of responsibility cannot be realized solely through efforts aimed at awareness-raising. The development and achievement of a culture of responsibility requires additional capacities, such as reflection and action,

to handle tasks and situations that may arise in dual use scientific research. Dual use ethical competence therefore entails more than simply knowing ethics; it implies capacities that enable individuals to also develop and apply their knowledge in ethically challenging situations.⁹

21. Developments in science and technology could clearly have implications for the operation of the Conventions, and processes have been developed for regular review of relevant scientific and technological advances. These take a somewhat different form for the two Conventions, but in both cases provide an opportunity for the scientific community to have input. The Chemical Weapons Convention has a Scientific Advisory Board to provide advice on relevant scientific and technological developments, including through reports to its Conference of the States Parties. The Conference of the States Parties is required to review scientific and technological developments relevant to the operation of the Convention, particularly during its Review Conferences, which generally take place every five years.

22. Within the BTWC, scientific and technological review also takes place during Review Conferences, based on reports from its States Parties, and more recently from its Implementation Support Unit. States Parties to the Convention also hold Annual Meetings (preceded by Expert Meetings) within an Intersessional Process. For the period 2012-2015, review of scientific and technological developments is a standing agenda item in this process. Under this agenda item, States Parties are considering: positive and negative impacts for the Convention from scientific and technological advances; potential reform of the science and technology review process; and support of national implementation through education, codes of conduct and other measures to encourage responsible conduct of the life sciences¹⁰.

23. Concerns have been raised that these processes are neither frequent nor comprehensive enough to adequately inform States Parties about relevant advances and possible forms of response. As possible revisions to the processes are discussed, there is a clear role for advice from scientists on e.g. how frequently such reviews should take place, what sort of evidence they should be based on, and what the future role of scientists within such processes should be (see Chapter 11).

Biorisk management

24. Biorisk management is a term used by the World Health Organization to cover activities in laboratory biosafety, biosecurity and safe transport of infectious substances. It includes general sets of guidance and standards:

- i. The Laboratory Biosafety Manual¹¹;
- ii. Biorisk Management: Laboratory Biosecurity Guidance¹².
- iii. Guidance on Regulations for the Safe Transport of Infectious Substances¹³;
- iv. Responsible Life Sciences Research for Global Health Security¹⁴.

25. The World Health Organization's biorisk management materials also include provision of training and more specific guidance relevant to particular disease outbreaks. These documents also aim to promote particular scientific practices through changes to culture and responsible science:

One of the goals of the biorisk management approach is to develop a comprehensive laboratory biosafety and biosecurity culture, allowing biosafety and biosecurity to become part of the daily routine of a laboratory, improving the overall level of working conditions and pushing for expected good laboratory management.¹⁵

26. The World Organisation for Animal Health provides similar guidelines in Chapter 5.8 – International Transfer and Laboratory Containment – of its Terrestrial Animal Health Code¹⁶ and Chapter 1.1.3 – Biosafety and Biosecurity in the Veterinary Diagnostic Microbiology Laboratory and Animal Facilities – of its Manual of Diagnostic Tests and Vaccines for Terrestrial Animals¹⁷.

27. Some of the measures and procedures detailed within the World Health Organization's Laboratory Biosafety Manual are well known – e.g. the use of risk groups for microorganisms and assignment of work to particular biosafety levels, alongside recommended practices and equipment to be used at each level. The existence of such international reference documents may assist international collaborative work, by providing for common standards and procedures across the groups involved. Any work involving (potentially) pathogenic microorganisms or

other biological material should apply the procedures outlined in these guidance documents, and they entail particular individual as well as institutional responsibilities and actions. The guidance on safe transport of infectious substances does not only apply to those transporting biological materials – it also applies to the sender and recipient.

28. It has been several years since the Laboratory Biosafety Manual was last updated (2004), and since the adoption of the Laboratory Biosecurity Guidance (2006); the scientific community can contribute to their review and revision, e.g. by providing advice through national government departments. The Laboratory Biosecurity Guidance strongly emphasises the need for biorisk management approaches to be developed at the institutional level, in order to be appropriate to local conditions and facilities:

A specific laboratory biosecurity programme managing the identified biorisks, should be prepared and designed for each facility according to its specific requirements, to the type of laboratory work conducted, and to local and geographical conditions. Laboratory biosecurity activities should be representative of the institution's various needs and should include input from scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, law-enforcement agencies and security staff if appropriate. (p.7)

29. The World Health Organization's Laboratory Biosecurity Guidance also emphasises the importance of good quality interactions with local emergency responders. It is clear that individuals have a key role in helping to ensure that work is conducted safely and securely, based on up-to-date evidence and knowledge about local conditions and practices. The World Health Organization is also keen to engage with scientists, as it develops and promotes implementation of its Strategic Framework on Laboratory Biorisk Management¹⁸.

30. The World Organisation for Animal Health's codes and manuals are regularly reviewed by its specialist commissions, with recommended updates adopted on a

routine basis by its governing body (known as the World Assembly, see Box 18.1). The specialist commissions have a small expert membership. Broader engagement opportunities are offered through international conferences, an in-house peer reviewed journal (the Scientific and Technical Review¹⁹), and through expert networks, including its reference laboratories and collaborating centres (which act as centres of expertise for particular diseases, research areas, or laboratory techniques).²⁰ The World Health Organization has over 700 research institutes designated as collaborating centres for the support of its work²¹.

Box 18.1: Illustrative example: process from international governance to impacts on individual activities – the World Organisation for Animal Health.

- i. The Biological Standards Commission decides that additional guidance on biorisk analysis needs to be added to the Terrestrial Manual, and produces a draft for comment by member states.
- ii. To assist its work on revising the draft, an ad hoc technical expert group is set up, and reports back to the Commission.
- iii. The Commission adopts a revised draft chapter (and accompanying guidelines), and recommends its adoption to the World Organisation for Animal Health's World Assembly (its governing body).
- iv. The World Assembly adopts a decision to add the new material to the Manual.
- v. The new material is added to the online version of the Manual; it will be added to the next paper edition, once that is approved.
- vi. The relevant national government department / veterinary authority issues new guidance to veterinary laboratories.
- vii. The management of veterinary laboratories develop new procedures and provide training for staff.
- viii. Individual staff at the laboratory adopt new practice, in line with the international standard.

(This is a simplified summary of a recent case in the OIE, which added two sections to the Terrestrial Manual²²: Chapter 1.1.3.a Standard for managing biorisk in the veterinary laboratory and animal facilities; and Guideline 3.5 Managing biorisk: examples of aligning risk management strategies with assessed biorisks.)

Disease control

31. As explained in Chapter 7, governance for disease control purposes can contribute to the management of deliberate as well as natural outbreaks. Governance measures have been adopted to control transboundary movements of pathogenic material and, more broadly, to minimise the risk of transboundary disease, spread through international travel and trade. Broadly, the World Health Organization is responsible for managing threats to human health; the World Organisation for Animal Health for animal health; and the Food and Agriculture Organization for plant health. The three organisations also make efforts to coordinate their work in key areas of overlap (e.g. the human-animal disease interface, or food and feed safety). The organisations provide regulations:

- i. The International Health Regulations²³;
- ii. The Terrestrial Animal Health Code²⁴, Aquatic Animal Health Code²⁵, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals²⁶, and Manual of Diagnostic Tests for Aquatic Animals²⁷;
- iii. The International Plant Protection Convention²⁸.

32. These rules may affect scientific work which requires the transboundary movement of pathogenic material; they also direct work towards surveillance and response objectives. Opportunities for input from scientists into these rules include participation in research networks and standard-setting processes, and contribution to in-house scientific publications.

33. These organisations also convene surveillance and response mechanisms / networks, which make use of scientific expertise and data, including:

- i. The Food and Agriculture Organization's Emergency Prevention Systems for animal health,²⁹ food safety,³⁰ and plant protection;³¹
- ii. The Global Early Warning System for Major Animal Diseases³², which combines information mechanisms from the three organisations;
- iii. The World Health Organization's Global Outbreak Alert and Response Network³³, and Global Influenza Surveillance and Response Network;³⁴

- iv. The Food and Agriculture Organization and World Organisation for Animal Health's Network on Animal Influenzas;³⁵
- v. The World Animal Health Information System,³⁶ for member states to exchange information and report outbreaks, and the World Animal Health Information Database,³⁷ which provides its public interface.

Protection of biodiversity

34. Biodiversity can also be threatened by transboundary movements of animals, plants and microorganisms. The concern in this area is not just about pathogenic material, it covers other threats such as invasive species, and the possibility of gene transfer from genetically engineered organisms. The Convention on Biodiversity and its Cartagena Protocol on Biosafety partly aim to address such threats; they also promote application of modern biotechnology in ways which support conservation of biodiversity and sustainable use of its components, and support capacity building for this purpose.

35. As mentioned in Chapter 7, the Cartagena Protocol on Biosafety has an advance informed agreement procedure relating to transboundary movements of living modified organisms³⁸, which may have an impact on international research collaborations which e.g. require import of a living modified organism for a field trial. More generally the Convention on Biodiversity and Cartagena Protocol require use of environmental risk assessments, where projects may have significant impacts on biodiversity – scientists will be involved in the conduct of such risk assessments, and could e.g. advise on suitable procedures to use, and standards of evidence to apply.

36. A key route for scientific input into the development and implementation of the Convention and its Protocols is through its Subsidiary Body on Scientific, Technical and Technological Advice – the process for which is outlined in Box 18.2. In 2012 an Intergovernmental Platform on Biodiversity and Ecosystem Services was also launched, in order to strengthen scientific input into policy on sustainable development, through the creation of a group of experts who will conduct assessments of existing scientific information and knowledge, and present them for use in policy-making.

Box 18.2: Illustrative example: process for scientific input into international governance – the Convention on Biodiversity’s Subsidiary Body on Scientific, Technical and Technological Advice

- i. A new area of converging science and technology – synthetic biology – becomes increasingly prominent.
- ii. Academies, funders, journal editorials, and non-governmental organisations raise questions about whether synthetic biology is sufficiently covered by existing rules.
- iii. The issue comes to the attention of national policy-makers, who instruct their representatives to raise it as an issue within the relevant body (the Convention on Biodiversity’s Conference of the Parties).
- iv. The Conference of the Parties decides that the Subsidiary Body on Scientific, Technical and Technological Advice should examine whether synthetic biology is a ‘new and emerging issue’ which it should consider further.
- v. The Convention on Biodiversity Secretariat produces background documentation on synthetic biology to support the Subsidiary Body’s decisionmaking, and subjects it to consultation, revision and further consultation.
- vi. States, scientific groups, academies and non-governmental organisations submit comments and background information during the consultation periods.
- vii. Based on the comments received, the revised document is considered by the Subsidiary Body, which recommends that the next Conference of the Parties adopt a decision calling for a precautionary approach to be adopted, while a more robust analysis of the topic is conducted.
- viii. The Conference of the Parties adopts a revised version of the decision, recommending a precautionary approach be adopted by states, and establishment of an ad hoc technical expert group to support further analysis of the issue.

(Based on a real example of work of the Subsidiary Body. The relevant background documents and decisions can be found at <http://www.cbd.int/emerging/>.)

Summary: how scientists can participate in international governance

37. There are various reasons why individuals might choose to play a role in the development and implementation of international governance. Some of these relate to ensuring that it is appropriate to scientific practice, and that its impacts are justified and not unnecessarily burdensome or restrictive:

- i. Concern that international governance is not appropriately addressing scientific needs or lacks an appreciation of its impacts on practice;
- ii. Concern that governance measures are not based on scientific evidence;
- iii. Concern that governance is not keeping pace with scientific advances.

38. It may also be viewed as a part of scientific responsibility. It is now broadly recognised that scientific responsibility relates not only to the conduct of scientific work, but also extends to the relationship between science and society³⁹. In relation to the international governance of science, there are reciprocal responsibilities for scientists and society. Society (through its governmental representatives) is expected to get governance right, in terms of facilitating scientific contributions to addressing (global) social challenges; in turn, scientists are expected to provide evidence and advice to support the selection of appropriate policy responses.

39. Scientists can participate in international governance as individuals (e.g. through membership of expert networks or review bodies, contributions to consultations) and as collectives (e.g. through representative bodies such as science academies). These contributions can be made at a national level, contributing both to the development of negotiating positions of governmental representatives to international organisations, and to how national implementing measures are developed and applied (including through participation in e.g. laboratory biosafety and biosecurity boards at an institutional level). Contributions can also be made directly into some of the processes at the international level. Internationally there are also groups that collectively represent science academies and actively provide input into such processes. These include, for example, the International Union of Pure and Applied Chemistry, the InterAcademy Panel, and the International Council for Science.

How to start contributing to international governance:

- i. Awareness – as a starting point, awareness of the rules that are relevant to your work, so that you can apply them in an appropriate way; and consideration of the impacts they have, in order to judge whether adaptation is needed.
- ii. Understanding – combined with understanding of processes of negotiation, development, and implementation of international governance, and identification of the points at which there are opportunities for scientific input.
- iii. Sharing awareness and understanding – building collective awareness and understanding through communication with colleagues and peers.
- iv. Provide an individual response or contribute to collective responses to policy consultations and requests for advice e.g. in the United Kingdom this may be through groups like the Royal Society of Biology⁴⁰ and the Nuffield Council on Bioethics⁴¹; at the international level this includes e.g. consultations of the Biodiversity Convention’s Subsidiary Body on Scientific, Technical and Technological Advice.
- v. Provide information (again either individually or collectively) to national government departments, which both represent the government in international organisations, and have responsibility for devising and implementing national policy changes.
- vi. Submit policy-related opinion or comment pieces to relevant journals.
- vii. Participate in expert networks or collaborative groups connected to particular rules / organisations.
- viii. Participate in capacity-building activities, for example joining international collaborative projects, providing open-access to data, and publishing in journals that are part of international access initiatives⁴².

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Chapter 19: Immersing students in responsible science through active learning pedagogies: lessons from education institutes in the MENA Region

Lida A. Anestidou and Jay B. Labov

Key learning objectives

- i. Understand and articulate differences between traditional and active learning pedagogies.
 - ii. Appreciate the importance of constructing assessments that align with, and reinforce, the learning goals for the module or course.
 - iii. Explore the elements of backward design when developing modules or courses.
 - iv. Explore ways to help students become more responsible for their learning, by reorganising the structure of modules or courses.
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1. The primary audience for this chapter is faculty who teach undergraduate courses, modules or curricula on biosecurity and/or responsible conduct of science, and who are interested in using evidence-based effective pedagogical approaches.
 2. The secondary audience is undergraduate students who may encounter active learning techniques for the first time in this book, or who are considering careers in teaching.

Chapter Overview

3. This chapter presents what the authors have learned from education institutes that to date have engaged more than 150 science faculty and research scientists from the Middle East/North Africa and from South and Southeast Asia in exploring research integrity, scientific misconduct and research with dual-use potential.

Two Classroom Scenarios for Engaging Undergraduates in Learning about Responsible Conduct of Science

4. In your module or full-semester course on scientific misconduct you elect to use as your example the current controversy about whether it is safe to immunise children against common childhood diseases. The pedagogical approaches that this example illustrates may be incorporated at any time in the course. However, research suggests that doing so consistently from the beginning of the course, especially for college students in their first or second years of matriculation, indicates that such approaches are common rather than exceptional, and will enable students to practice learning skills engendered by such an approach.

Teaching Approach, Scenario 1

5. The instructor begins the class: “Good morning, everyone! Today we are going to consider a well-known and well-studied incident that took place in the mid-1990s. The handout I distributed at the beginning of class (see Box 19.1 and Table 19.1 below) summarises what happened and why the scientific community deemed the scientist’s actions to be misconduct. We’ll review each point in class today, and I’ll make clear to you why each of the scientist’s actions was labelled as such. You can review everything tonight, and I will test you on your recall of the facts and the outcomes of this case as part of the mid-term examination next month (an example of possible test questions is in Table 19.2).

“Your performance on those questions will constitute 25 percent of your final grade.

“Here is some initial background information for our discussion today:”

Box 19.1: Background information

Dr. Andrew Wakefield, an internationally renowned and respected medical scientist, published a paper which concluded that autism may be caused by vaccination of young children with the widely given measles/mumps/rubella (MMR) vaccine, and that the likely culprit was a mercury-based compound (thimerosal) used to stabilise and prolong the shelf life of this vaccine. The publication of this paper has resulted in a clear reduction of vaccinations of young children across the world, and especially in developed countries. As a result of subsequent studies that could not replicate these results and other investigative work, it was discovered that this researcher engaged in a range of practices that were deemed to be scientific misconduct; this resulted in a series of professional sanctions for the researcher, including retraction of the paper by the editors of the professional journal (the Lancet, a highly-respected and authoritative medical journal in Great Britain¹) in which it was published. However, most people who continue to refuse to vaccinate their children do not know about the misconduct.

Table 19.1: Some of the alleged irresponsible conduct of science and classifications of scientific misconduct in the study connecting Thimerosal in vaccines to increased incidence of autism¹

Alleged Misconduct	Type of Misconduct
The scientist reported only those cases that supported his hypothesis and not those which didn't	Falsification of data
His research was supported financially by attorneys and parents seeking to sue the vaccine manufacturer for damages	Financial conflict of interests
Subjected research subjects to unnecessary medical procedures to obtain data	Medical malpractice

Patented a new vaccine for measles that could be widely adopted if the MMR vaccine were to be discontinued	Financial conflict of interests
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Table 19. 2: A sample of possible exam questions for this module

<p>1. What was the specific vaccine on which the research in question was conducted?</p> <ul style="list-style-type: none"> i. Measles (rubeola) ii. Mumps (parotitis) iii. Measles/mumps/rubella (German measles) iv. Pertussis (whooping cough) v. Varicella-zoster (chicken pox) <p>2. Which of the following forms of scientific misconduct was NOT identified or alleged in this incident? CIRCLE ALL THAT APPLY:</p> <ul style="list-style-type: none"> i. conflict of interest ii. misuse of research subjects iii. falsification of data iv. fabrication of data v. plagiarism <p>3. In not more than THREE PARAGRAPHS, prepare an essay that:</p> <ul style="list-style-type: none"> i. states the facts behind the case ii. provides THREE reasons that the research is alleged to be fraudulent iii. explores one of these issues in greater detail, indicating whether you agree or disagree that this practice constitutes misconduct. <p>BRIEFLY DEFEND YOUR ANSWER.</p>
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Teaching Scenario 2

6. The instructor begins the class: “Good morning, everyone! Today we are going to consider a well-known and well-studied incident that took place in the mid-1990s. During class today we’re going to examine different aspects of this case [see Box 19.1 above]. Some, but not all, of the questions we’ll consider are provided in the handout that I distributed at the beginning of class (see Table 19.3 below). We’ll review each of these in class today, as a prelude to a far more extensive consideration of this case between now and the next two classes. We’ll also continue to refer back to this case throughout the course to examine different ways in which misconduct can be manifest, how easy it is to engage unknowingly or unwittingly in various forms of scientific misconduct, and how, by being aware of such practices, you – as future scientists and engineers, or those of you who will work with scientists and engineers in some other capacity – can establish a career of great accomplishment and scientific integrity.

7. “By the time we have finished this section of the course, you should be able to demonstrate your knowledge of the nature and scope of scientific misconduct, by reviewing a case study of my choosing with other people in your work group, prior to the next exam. The exam itself will contain questions about the methodologies employed in the research, the authors’ interpretation of data, and other issues that we raise collectively during class. You also will be given the opportunity to write about what you might consider to be examples of other kinds of misconduct (and your rationale for doing so). Prior to that exam, you’ll have opportunities to work through cases and scientific papers to develop your skills in this kind of analysis.² I will also provide you with guidance about how the exam will be scored, so that you will understand the level of knowledge and understanding, and the specific competencies that I am expecting you to demonstrate.

8. “As our discussions proceed in class, please make a decision about how you would classify each type of alleged misconduct. We’ll use the iClickers™² for this class to vote on whether you consider each of the allegations to be misconduct or not. After we examine the results of your voting, you will turn to your neighbour and discuss the basis for your votes. We’ll then use the iClickers™ again to determine whether

opinions about misconduct in this case have changed. We will use those instances where we uncover disagreements in the class as a starting point to use other parts of this book, along with other published sources, to determine whether the scientific community has reached consensus on what falls under various categories of misconduct. Additional instructions will be provided in class and in handouts about next steps for completing this exercise.”

Table 19.3: Alleged irresponsible conduct of science in the study connecting Thimerosal in vaccines to increased incidence of autism

Alleged Misconduct	Is this a form of Misconduct?	If yes, what kind of misconduct?
The scientist reported only those cases that supported his hypothesis and not those which didn't.		
His research was supported financially by attorneys and parents seeking to sue the vaccine manufacturer for damages.		
Subjected research subjects to unnecessary medical procedures to obtain data.		
Patented a new vaccine for measles that could be widely adopted if the MMR vaccine were to be discontinued.		
Others? Please enter your own conclusions about other forms of misconduct.		

How Do These Two Teaching Scenarios Differ?

9. In each scenario the instructor begins with presenting the same set of facts of the case. However, the type and level of learning expected, the roles that students will play in constructing their knowledge, and the extent to which they are expected to be responsible for that learning, are dramatically different. Let's examine these differences in greater detail:

10. Scenario 1 describes many undergraduate classrooms and seminars by emphasising "teaching by telling," where the instructor and her/his handouts (Table 19.1) serve as the primary source of knowledge and authority. Students are told the answers and then asked to demonstrate their knowledge by taking an examination that seeks straightforward recall of "facts". The professor provides no background or context as to why it is important for students to understand this material, other than to show mastery of recall on the test. The structure of this exercise emphasises the role of the individual learner, rather than the benefits of interaction among the learners.

11. Indeed, in this scenario the instructor tells students that lower level of knowledge is what is expected and thus the norm; but in reality this information is highly complex, answers that demonstrate deep understanding need to be multifaceted and nuanced, and there often is no one right answer, because deciding that certain professional behaviour constitutes misconduct is often contextual, and sometimes related to norms and expectations that may differ among cultures. We contend that, even if students answer all questions correctly, their seemingly excellent performance is actually a poor proxy for the far more conceptual learning that is needed to actually demonstrate their grasp of this material. Even in question 3 of the sample exam (Table 19.2), students are led through the various parts of questions that require low level cognitive learning. The first question asks students only to remember the correct answer. The instructor may think that including scientific names for each of these diseases listed as possible answers may raise the learning level of the question; but if students have not had opportunities to study them, inclusion of technical terms could be viewed as an attempt by the instructor to confuse. Question 2 appears to require that students understand the differences among these different types of research misconduct, but the question can be answered simply by memorising the information

in Table 19.1. While Question 3 asks students to provide their answers in short essay format, the first two parts of the questions simply require students to write out facts that they have recalled, rather than circling answers. The only part of this exam that requires demonstration of higher order thinking is the last part of question 3, where students are asked to state an opinion and then to defend their answer.

12. Moreover, the instructor does not give this exam until a month after s/he has 'covered' this material. With these questions counting as 25% of the final grade, this exam is clearly high stakes.³ However, until the exam takes place, the instructor has no way to determine whether students have actually mastered the material, even at low levels of understanding and performance, because there are no opportunities to demonstrate their learning through lower stake discussions in class, short papers, or tests that do not affect much or at all the final grades. Such types of formative assessments not only help students monitor their own progress, but also help instructors to determine the effectiveness of their teaching in helping students to learn, and then take corrective actions before students are expected to engage with higher stakes assessments^{4,5,6}.

13. In contrast, Scenario 2 differs in many important ways from Scenario 1. The instructor sets the tone for high level discussions from the beginning, by pointing out that some cases of misconduct may not be absolute, since it is easy for scientists to engage unknowingly or unwittingly in such behaviours. The professor also makes clear that learning this material is important, because it has direct relevance to students' establishing future careers "of great accomplishment and scientific integrity." The amount of time required to set this context is a few seconds, but the impact can be long lasting, because it provides students with the broader context for what they will study.

14. Further, the professor explains that s/he will not provide answers for an exam, but instead will serve as a coach and facilitator to help students construct their own understanding of the concepts. Thus the instructor's learning goals and objectives ("By the time we have finished this section of the course you should be able...") are presented so that the class understands how they will be assessed in the exam, how the quality of their answers will be scored (by providing guidance), and the tools they

will be provided, both in and outside of class, to enable them to practise and thereby achieve what is expected of them. Under this scenario, the materials that students receive (Table 19.3) are deliberately (and, for those not exposed to this kind of learning, maddeningly) open-ended.

15. In the prelude to the discussion on scientific misconduct (Table 19.3), the use of iClickers™, followed by discussion with classmates and re-voting, can spark the interest of most students to compare their own understanding of the material with that of others in the class. This exercise provides the instructor with real-time information about the level of understanding of the material at the beginning of the class, and whether students' perceptions are changing as discussion ensues.

16. Finally, learning under this scenario can take place in many locations. The classroom is only one of them. By encouraging both individual and group work and asking students to acquire lower cognitive level information outside of the classroom, more time can then be devoted in class to helping them grapple with the complexity of the responsible conduct of science, and more specific issues such as biosecurity.

Integrating Responsible Conduct of Science and Active Learning: Insights from the U.S. National Academy of Sciences' Education Institutes

17. The type of teaching and learning highlighted in Scenario 2 constitutes the focus of the educational institutes that the US National Academy of Sciences has organised for scientists and engineers from the Middle East/North Africa region (MENA) and from South and Southeast Asia. These institutes are based on recommendations from international conferences about the importance of improving education about responsible conduct of science^{7,8,9,10}; they are modelled on the long-established National Academies Summer Institutes for Undergraduate Education,¹¹ where college and university faculty have received professional development in employing active learning and assessments aligned to learning goals in their undergraduate science and engineering classes^{12, 13, 14}. These institutes have helped faculty recognise the differences in the teaching and learning approaches discussed above, and develop

their own active learning modules and aligned assessments to use in their own courses, or to help their colleagues engage with the responsible conduct of science (RCS).

18. The first institute on RCS was held in Aqaba, Jordan, in September 2012 for life sciences faculty from Algeria, Egypt, Jordan, Libya, and Yemen. Colleagues from the Great Library of Alexandria, Egypt¹⁵, helped the organising committee develop an agenda in response to attendees' cultural and professional needs. The outcomes and lessons learned from this institute^{16,17} (see also the summary below) informed the organisation of subsequent institutes in Kuala Lumpur, Malaysia¹⁸; Trieste, Italy¹⁹; and Istanbul, Turkey²⁰.

19. Each institute was scheduled for 5.5 days and included approximately 50 hours of active engagement in larger and smaller group settings. Institutes focused on three broad themes of RCS, illustrated by a series of case studies²¹: (1) Development of professionalism in science; (2) Conducting research responsibly; and (3) Being part of the responsible scientific community. Under these themes, sessions included various aspects of RCS, including falsification and fabrication of data; authorship and plagiarism; research with human and animal subjects; and research with dual-use potential,²² using Macrina (2005)²³ as a primary text for the 'content' sessions at the institute. Pedagogy sessions focused on the effectiveness of active learning^{24,25,26,27}; (see also Freeman et al., 2014 and references therein²⁸) as a pedagogical tool, and best practices in using active learning, including backward design^{29,30,31} and techniques for effectively engaging students^{32,33,34,35}. Presenters and facilitators explicitly integrated active learning techniques in all RCS sessions (e.g., writing high quality clicker questions around RCS³⁶), while pedagogical sessions stressed the evidence base for how people learn, and the implications of that research for teaching, including aligning formative and summative assessments. Committee members with separate expertise in RCS and active learning pedagogies worked in teams to organise the sessions using iClickers™, think-pair-share, role playing, jigsaw discussions, concept mapping, poster sessions, and whole group discussions.³⁷

20. During most afternoons participants worked in small groups with trained facilitators (committee members and others with appropriate expertise, many of

whom served as presenters, facilitators, or who attended one or more Summer Institutes prior to these institutes).³⁸ The goal of these sessions was to develop teachable units, with teaching and learning activities and assessments that participants could implement at their own institutions. Each small group presented its unit to the rest of the participants, followed by constructive evaluation by their peers and the committee members.

21. In a post-institute survey (see Figures 2 and 3 in Clements et al., 2013³⁹) participants indicated that the top two reasons for attending the Institute were to “become more involved with future efforts to improve education about the responsible conduct of research in my country” and “to discover tools, resources and best practices for incorporating evidence-based teaching techniques into my courses.” However, the survey also indicated that 1) the scope of topics and issues around RCS was too great, since many participants were unfamiliar with the concepts; 2) many participants were unfamiliar with active learning pedagogies; and 3) using English as the primary language was not easy.⁴⁰

Adjustments for Subsequent Institutes

22. The aforementioned feedback from the pre-and post-assessments and the post-institute survey, coupled with committee members' own reflections, led to some restructuring for the subsequent Institutes. While the three major themes were carried forward, the following changes were made.

23. Content: Fewer cases on RCS were presented, but with more depth. Replacing the five RCS cases used in the first Institute, two cases of international fame and with broad RCS ramifications have been used for the subsequent institutes.⁴¹ This change was made to reduce the breadth of knowledge required by the participants, but equally importantly to 1) emphasise that irresponsible practices are interconnected and can have international repercussions, and 2) reinforce the pedagogical approach to help learners develop conceptual frameworks, and transfer knowledge and expertise from one subject domain to another⁴². In addition, a movie night has been added to watch the film Contagion.⁴³ The following morning's session is now an exercise in which participants assume the roles of four different organisations represented in the film

(World Health Organization, Centers for Disease Control and Prevention, the media, and the public) who advise each other about their needs and perspectives.⁴⁴

24. Pedagogy: The committee increased its efforts to integrate and model active learning pedagogies in all sessions that focused on aspects of RCS.

Implications

25. Activities that mesh active learning pedagogy with education on RCS have a clear potential to help scientists globally. Participants at the regional Institutes stressed the importance of being aware of international RCS standards, to help them partner with the international scientific community that adheres to established norms of professional conduct. They also recognised the importance of sharing ideas with others, and working collectively to influence changes to policies that impact both science and education in their countries.

26. We suggest several ways in which these active approaches to teaching and learning RCS might be adapted to undergraduate education, using the information contained in this Guide:

27. RCS content could be incorporated in both introductory and upper-level courses, to provide a conceptual framework for the discussion of scientific topics in class. Such a session might consider RCS topics of the instructor's choosing, topics raised by students, or ones from the scientific or mass media, and for which there are no clear answers. Instructors could initiate such conversations by projecting a question, with responses that students could select using clickers or other response systems. The array of responses could prompt questions such as "what biology, other science, or non-science subject matter do we need to learn, to begin to address these questions?" Or, where students work with faculty on research projects, "how have these issues led to the development of the procedures that we have adopted (or that have been mandated) for our research space?"

28. Students can provide examples of actions they have observed, or consider, to be misconduct or misbehaviour in their work environment or, more broadly, in science.

These can help the instructor identify what some students consider to be unethical behaviour or practice. Other students in the class might not share the same view.

29. Institute participants spend concentrated time together that is unlikely to be possible in many undergraduate classes. However, honours or upper level seminars could allow students to engage more deeply with RCS case studies built around the experimental work that is the focus of the seminar. The continuous availability of information online allows instructors to assign research outside of class, and then use class time to explore these topics in much greater depth by employing active learning techniques.

30. Campus-wide or department-wide book or other reading assignments could focus on aspects of RCS and include discussions with guest scholars, showing and discussion of videos (see the example above using the movie Contagion), and other activities to supplement discussion of the readings that were selected.

31. Research has demonstrated the efficacy of active learning, along with other experiences such as engaging in discovery-based research^{45,46,47,48,49}, as possible strategies to spark students' interest in science, technology, engineering, and mathematics. Research has also demonstrated that uninspiring traditional teaching methods drive students away from science^{50,51,52,53}. Experience from the National Academies Summer Institutes and other professional development opportunities for faculty⁵⁴ indicate that, at least in the United States, faculty who receive sufficient pedagogical training in using active learning prefer this strategy over more passive forms of pedagogy, even though such approaches may be difficult to maintain⁵⁵. The use of active learning techniques is becoming increasingly common on U.S. campuses, generating the means for enhancing RCS training in the undergraduate curriculum.

32. Research is needed to determine whether active learning has the same impact in helping students in other educational environments. However, growing – but still limited – evidence from our education institutes in the MENA and Southeast Asia suggest that faculty in those regions, who have personally experienced this approach to teaching and learning, are eager to embrace it to help their own colleagues and

students engage more deeply with topics such as biosecurity in the broader context of RCS. All students, whether they opt for careers in science, or pursue careers that intersect with scientific disciplines, or who interact with science and technology as informed citizens, need opportunities to understand these concepts deeply, and to retain and internalise them.

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² As noted briefly in Chapter 3 (section 22), iClickers™ and similar devices are one of many types of radio frequency devices that enable students to provide anonymously to questions that instructors pose, say in multiple choice format. Students can change their answers as often as they wish during the period that responses are being collected; the last response that the student provides is the one that is registered with the final tabulation of responses. The associated software then displays a histogram of the responses when the instructor chooses to display them. Histograms from different voting sessions can also be juxtaposed to allow everyone in the class to compare responses. If clickers are not available, internet software now allows similar kind of voting by texting from cell phones (for example, Live Audience Participation (<http://www.polleverywhere.com/>)). Additional information about these kinds of devices and their effective uses is available in education journals such as CBE/Life Sciences Education (<http://www.lifescied.org/search?fulltext=clickers&submit=yes&x=0&y=0>).

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- ¹⁹ <http://twas.org/>; attended by faculty from Egypt, Iraq, Lebanon, Morocco and Yemen
- ²⁰ Attended by faculty from Iraq, Libya, Morocco and Turkey.
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Chapter 20: Interactive biosecurity education: Team-Based Learning in action

Tatyana Novosiolova

Key learning objectives

- i. Understand the need for combining content with strategy when teaching biosecurity.
- ii. Develop appreciation of the concept of active learning.
- iii. Gain an insight into the Team-Based Learning format, its key elements and advantages with regard to teaching biosecurity.

Interactive biosecurity seminars

1. In November 2012 the University of Bradford, together with the Landau Network-Centro Volta and colleagues from the University of Turin, Italy, and the University of Coimbra, Portugal, held an interactive biosecurity seminar on Bioethics and Responsible Research. The seminar used a cutting-edge teaching format, namely Team-Based Learning, which is briefly described in the next section. An outline of the seminar activities is available in Table 20.1. The seminar lasted about 3 hours and was hosted on the premises of the School of the Life Sciences¹ at the University of Bradford, with the explicit endorsement of the School's Dean. Thirty participants took part in the seminar, mainly undergraduate and postgraduate students from different courses, such as the life sciences, international relations, engineering and law, and a small number of tutors and biosecurity experts. From the outset, participants from different fields were divided into four teams, and an additional fifth team was formed by the tutors and the two biosecurity experts present at the seminar.

Table 20.1: Structure of the biosecurity Team-Based Learning seminar

Seminar Phases	Description	Bloom's Taxonomy ²
1. Pre-Reading Activity	<ul style="list-style-type: none"> i. A set of materials designed to give participants a general overview of the issues to be discussed at the seminar; ii. Disseminated about a week before the seminar. 	Remembering
2. Individual Readiness Assurance Test (iRAT)	<ul style="list-style-type: none"> i. Consists of multiple-choice questions based on the pre-reading materials, which aim to assess the extent of individual grasp of contents; ii. Takes the form of a closed-book exam; iii. Duration 15 minutes. 	Understanding
3. Team Readiness Assurance Test (tRAT)	<ul style="list-style-type: none"> i. Completed in teams using the same test as the iRAT; ii. Takes the form of a closed-book exam; iii. Duration 15 minutes. 	Applying
4. iRAT and tRAT Feedback Session	<ul style="list-style-type: none"> i. The results of the iRAT and tRAT are compared; ii. Challenging questions are clarified; iii. Takes between 5-10 minutes. 	

<p>5. First Team-Based Application Exercise</p>	<ul style="list-style-type: none"> i. Features a specific scenario related to the seminar topic, followed by a set of multiple choice options; ii. Working as a team, participants have to discuss the scenario, agree on an option, and provide a rationale for their choice; iii. Duration 20 minutes. iv. Feedback and discussion. 	<p>Analysing Evaluating</p>
<p>6. Second Team-Based Application Exercise</p>	<ul style="list-style-type: none"> i. A practical exercise, as part of which participants have to apply what they have learnt during the seminar to a particular task/problem; ii. Duration 25 minutes; iii. Feedback and discussion. 	<p>Analysing Evaluating Creating</p>
<p>7. Evaluation Questionnaire</p>	<ul style="list-style-type: none"> i. Consists of questions that seek to elicit participants' feedback on the quality, relevance and utility of the seminar; ii. Preceded by a debrief session that allows participants to share their immediate views on the seminar. 	

2. A week before the seminar a set of pre-reading materials was distributed among participants. The set consisted of the following:

- i. Summary of the 2004 National Research Council's report Biotechnology Research in an Age of Terrorism;
- ii. Summary of the 2006 National Research Council's report Globalisation, Biosecurity, and the Future of the Life Sciences;
- iii. Rebecca Carlson and Mark Frankel, Reshaping Responsible Conduct of Research Education, AAAS Professional Ethics Report, vol.24:1, Winter 2011, pp.1-3. Available at <http://www.aaas.org/sites/default/files/migrate/uploads/Professional-Ethics-Report-Delta.pdf>.

The chief objective of the pre-reading materials was to introduce participants to the issues of dual use and biosecurity, by providing a general overview of the main concepts and issues. All participants were advised that they should familiarise themselves with the pre-reading materials before coming to the seminar.

3. At the start of the seminar, the participants were given a short individual quiz (iRAT), featuring five multiple-choice questions designed to assess their foundational knowledge and understanding from the pre-reading materials, and prepare them for the subsequent problem-solving (application) exercises. The quiz that was used during the seminar is presented in Table 20.2. Following the individual test, participants were asked as a team to answer the same questions. In this way, they could discuss which answer should be chosen, and thereby clarify each other's understanding of the issues involved. After the individual test and the team test had been completed, participants then had the opportunity to raise questions and make comments on what they had found easy/challenging, and to ask for further clarification from the seminar facilitators.

Table 20.2: Individual Readiness Assurance Test (iRAT) and Team Readiness Assurance Test (tRAT) sample questions

Questions	Multiple Choice Options
1. Which of these statements best defines the dual-use dilemma?	a) Research that has both civilian and military application b) Research that has multiple

	<p>applications</p> <p>c) Research that can be legitimately used for human betterment and, at the same time, misused for malevolent purposes</p> <p>d) Research that could be used more than once</p> <p>e) Research that could potentially have more than one end user</p>
<p>2. Which of the following statements about the dual-use dilemma is true?</p>	<p>a) It does not raise any security concerns</p> <p>b) The scientific community is well aware of it</p> <p>c) It is covered by existing international and national policies</p> <p>d) The results of such research may facilitate hostile misuse</p> <p>e) Such research is covered by comprehensive international and national regulations</p>
<p>3. Which of the following is <u>not</u> among the recommendations of the Fink Committee Report <u>Biotechnology Research in the Age of Terrorism</u>?:</p>	<p>a) Dual-use research should not be published, or otherwise publicly disseminated</p> <p>b) The science community should be educated about the dual-use dilemma</p> <p>c) Experiments that would enable the weaponisation of a biological agent should be subject to additional review before being performed</p> <p>d) Harmonised international system for oversight of the life sciences</p>

	<p>should be implemented</p> <p>e) Certain types of experiments should not be performed before they have undergone additional review</p>
<p>4. The Lemon-Relman Committee Report <u>Globalisation, Biosecurity and the Future of the Life Sciences</u>:</p>	<p>a) Highlighted the potential health and economic benefits of biotechnology, rejecting any potential security issues</p> <p>b) Substantially expanded the threat spectrum to cover different branches of the life sciences, including pharmacology, synthetic biology, systems biology etc.</p> <p>c) Was designed to give an overview of the different applications of nanotechnology</p> <p>d) Focussed exclusively on developments in microbiology</p> <p>e) Avoided mentioning any security issues that may arise from the proliferation of novel technologies</p>
<p>5. In what way should the responsible conduct of research (RCR) education be reshaped to reflect the changing role of science in society?</p>	<p>a) No need for change, it is good enough as it is</p> <p>b) It should focus only on aspects related to the practice of life science research</p> <p>c) It should cover only examples of scientific misconduct, e.g. falsification, fabrication and plagiarism</p> <p>d) It should concentrate on issues arising in the conduct of science,</p>

	<p>rather than on its social influence</p> <p>e) It should require life scientists to consider the social, ethical and legal implications of their work</p>
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4. In the second half of the seminar, participants were given two problem-solving tasks that aimed to enhance their understanding of dual use and biosecurity, through the practical application of the knowledge they had acquired thus far. The first exercise constituted a short scenario based on a real life dual use controversy, namely the debate on the creation of highly pathogenic Avian Influenza (H5N1) virus (see Chapter 2). Whilst the scenario draws upon the elements of the 2011 controversy, it is written in a simplified form aimed to provoke discussion. As such, it does not constitute a factual account of the controversy. The scenario is presented in Box 20.1. Participant teams were required to read through the scenario text, and then to choose, from the seven options provided, what the best possible outcome of the controversy would have been. In doing so, they were required to discuss the scenario, debate each possible option, and reach group consensus on the best possible outcome. They had to complete the task within 20 minutes. All teams were then required to announce their decision at the same time using a designated card, and then give a rationale for their choice, elucidating the reasoning behind their group decision. This was followed by a vigorous discussion on the different perspectives put forward.

Box 20.1: First application exercise: multiple-choice scenario

In September 2011, a team of scientists from the University of Rotterdam in the Netherlands announced at a conference in Malta that they had successfully created a highly virulent mammalian-transmissible lethal strain of the H5N1 bird influenza virus. The story quickly got picked up by popular science media, and by December the deadly sensation was in the spotlight worldwide. At about the same time, the National Science Advisory Board for Biosecurity (NSABB), a consulting body with an advisory capacity to the US Government,

recommended that the research results detailing how the lethal virus was created should be published in a redacted form, in order to prevent replication by individuals or governments with malevolent intent. Full information on the methods and materials used in the study, the Board maintained, should only be disclosed to those who need to know, so that the benefits could still be obtained and security guaranteed. In the debate that followed, it became clear that the scientists leading the H5N1 experiments were utterly unaware of the potential biosecurity, ethical and legal concerns arising from their work.³ Reaching consensus was further hampered by the fact that no mechanisms were in place for the dissemination of the research on a 'need-to-know' basis. In late March the US Government stepped into the debate by issuing a policy for research review, which made provisions for the possible classification of high-risk scientific research. Around this time, the NSABB reversed its position, allowing the publication of the Dutch study in the journal *Science*.

Was there a better way to handle the H5N1 controversy? Which of the options below best summarises your view?

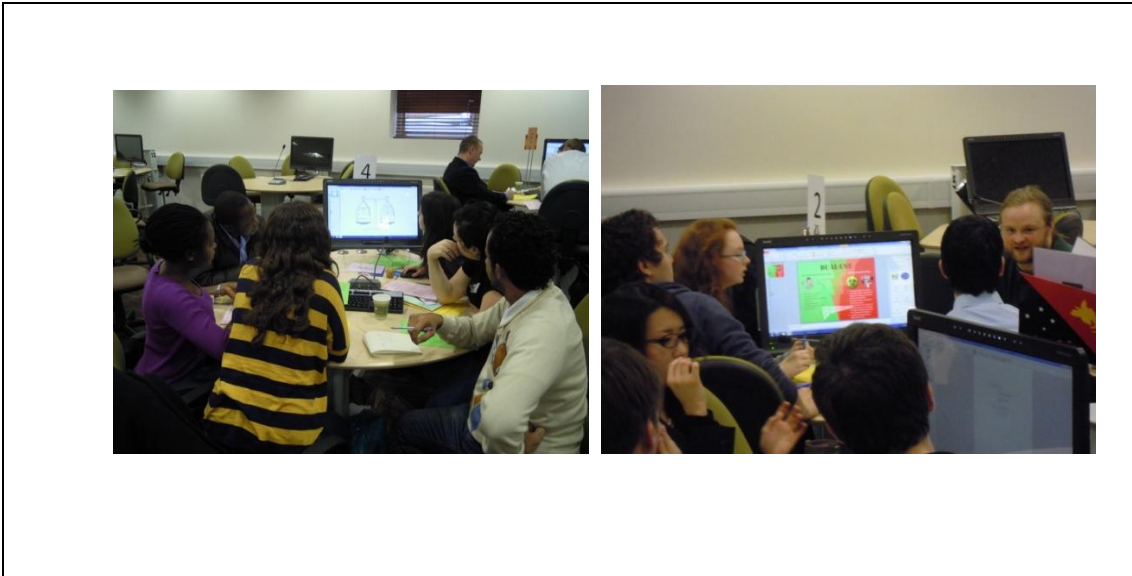
- A. The debate was unnecessary; the experiments should have been published in full straight after the Malta meeting
- B. The debate was too lengthy, but otherwise it was successfully resolved in favour of science; governments should not interfere with the work of scientists
- C. Popular media is to be blamed for the prolonged debate: had they not exaggerated the story, the debate could have been avoided
- D. The Dutch scientists should have not shared the research in Malta, but should have published it quietly in Science, without flagging any dual-use

or biosecurity issues

- E. The Dutch scientists should have considered the potential biosecurity concerns of their work, and carefully addressed these in the manuscript, before submitting it for publication
- F. The Dutch scientists should have been aware of the dual-use potential of their work when the experiment was first conceived, and they should have conducted a careful risk-benefit analysis of whether to conduct the work at all
- G. The Dutch scientists should not have conducted the experiment in the first place
- H. The paper should have been classified immediately after it was submitted for publication

5. The second application exercise sought to build upon the arguments and issues addressed in the preceding discussion, encouraging participants' creativity and imagination. As part of this task, the teams had to develop a poster design to raise awareness of dual use and biosecurity (Box 20.2). Each team was then asked to elaborate on the ideas expressed on their posters, and subsequently to vote for the poster they liked most. A competitive element was added to the exercise, as the best two poster designs were to be developed into full-scale posters, and possibly presented at the BTWC Meeting of Experts in August 2013 in Geneva. The exercise was followed by a debriefing session on the overall quality and usefulness of the seminar.

Box 20.2 Student teams working on posters as part of the second application exercise



6. At the end of the seminar the participants were asked to answer questions regarding their seminar experience. The scope of the questions covered both the seminar itself and the topic of dual use and biosecurity. The list of questions comprising the questionnaire is presented in Table 20.3.

Table 20.3: Questions included in the post-seminar questionnaire

Questions
1. What did you gain from the session today?
2. Has your understanding of team and group work changed? If so, how?
3. What are the important things to remember about 'Dual-Use'?
4. Are there any other comments you'd like to feedback about today's session?

Why Team-Based Learning for biosecurity?

7. Team-Based Learning (TBL) is a special form of collaborative active learning, that uses a specific sequence of individual work, group work and immediate feedback to create a motivational framework, whereby the focus is shifted from the conveying of concepts by the instructor, to the application of concepts by student

teams.⁴ Definitions aside, the positive feedback received from participants in three independently-held TBL seminars – in Bradford, Rabat (see Box 20.3),⁵ and Amman (see Chapter 15) – clearly illustrates that active learning approaches, and TBL in particular, are an effective strategy for engaging life scientists on biosecurity. The data presented in Figure 20.1 and 20.2 indicate the advantage of active learning and TBL vis-à-vis traditional lecture-based teaching methodologies. The results of the second questionnaire described above are shown in Table 20.4.⁶

Box 20.3: TBL Seminar at the University of Mohammed V-Agdal, Rabat, Morocco: Student teams presenting their posters as part of the Second Application Exercise



Figure 20.1: The responses to “Which of these statements best defines the dual-use dilemma?” at six 2012 EU Biosecurity Awareness-Raising Network (BARnet) Seminars: 45 participants in active learning seminars at the University of Bradford and Delft Technical University⁷ vs. 165 participants in lecture-based seminars at the University of Milan, Turin, Coimbra, and Granada.

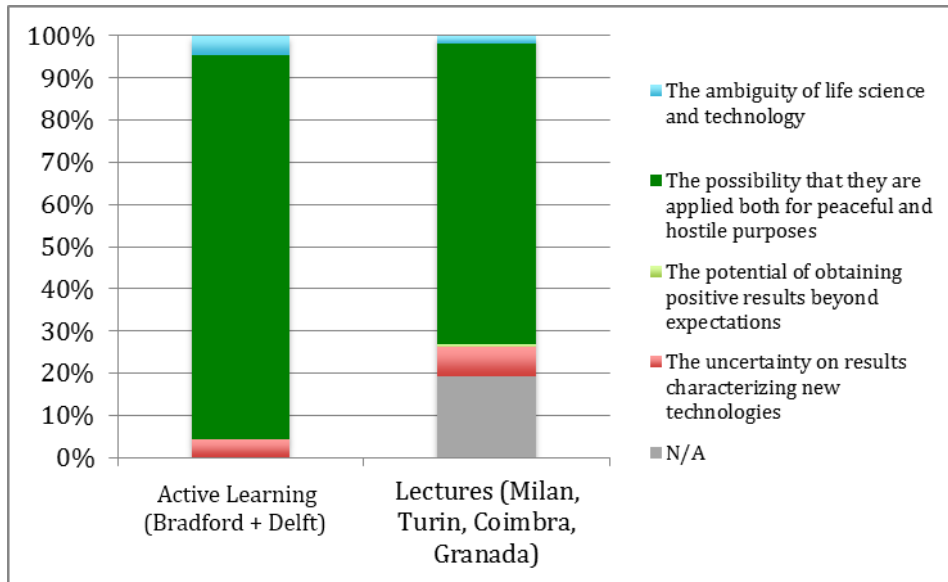


Figure 20.2: The responses to “Which of these statements best defines the dual-use dilemma?” 30 participants in Team-Based Learning at the University of Bradford vs 210 participants in non-Team Based Learning seminars at the University of Milan, Turin, Coimbra, Granada, and Delft Technical University.

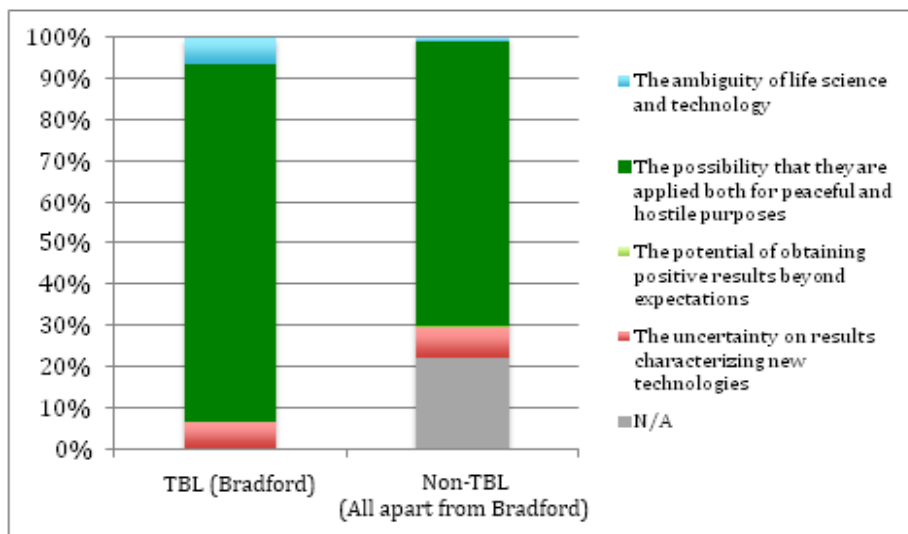


Table 20.4: Answers to the post-seminar questions

Question	Type of Answer	Mentioned by %	Examples	
What did you gain from the session today?	Better understanding of research and science ethics	21%	“Basic understanding/knowledge of possible procedures to reduce risks”	“A greater grasp of the perspective of life sciences students on ethics”
	Better understanding of the dual use, misuse and security issues	34%	“Got an understanding of this underlying idea of dual use and what can be done to reduce the abuse of scientific research.”	“A better grasp of how the dual-use dilemma is and isn’t understood by scientists”
	Insights on TBL	41%	“An alternative innovative and engaging learning technique and format”	“A nice interactive programme”
Has your understanding of team and group work changed? If so, how?	Interdisciplinarity helps bringing different views	21%	“Working with people with different interests to you can help show different views of the same topic”	“The varied background of the group helped bring different opinions and perspectives in the disputes”
	Enjoyed teamwork, interaction and TBL	34%	“I now see that bringing ideas together is always a positive way of discussing”	“Mistakes can easily be identified”
	Helps to overcome individuality and be open	7%	“Need to be open to other people’s opinions, and to allow them to persuade you.”	“Need to be able to evaluate opinions”
	My understanding did not change	34%		
What are the important things to remember about	Awareness among scientists is important	38%	“Awareness of the dual-use would provide the best safeguard in my	“Need of increasing the awareness of it and popularising among the

Dual-Use?			opinion"	scientific society"
Early risk consideration and assessment is important	21%		"Needs consideration before research"	"Think, before doing any research study, to its future impact in society and nature"
The issue is very complex	10%		"The complexity of this issue, and its impact on everyday life in the future"	"There's a very blurry line between benefits and risks"
There are potential risks and impacts on society to consider	41%		"Carefulness: benefits as well as risks"	"Scientists should be really careful about the way their research can be used besides their main idea"
Freedom of research/publication is important	7%		"Should not stop searching in the face of the problems"	"Risk assessment and the importance of publicity on research"

8. In 2010 the US National Academy of Sciences(NAS) published a report⁸ entitled Challenges and Opportunities for Education about Dual Use Issues in the Life Sciences, which describes ‘the extent to which dual use issues are currently included in postsecondary education in the life sciences; the contexts in which education is occurring; and what needs exist that must be addressed to enable significant expansion of education of dual use issues.’ In regard to the development and implementation of biosecurity education programmes, the report highlighted the importance of two themes. First, it reiterated⁹ the point that biosecurity concerns related to work with dual-use potential and “social and ethical responsibility ... can readily be integrated in laboratory learning, whether it is a formal undergraduate laboratory experience or graduate-level research.” The NAS report made the point that these concerns could be approached within the framework of responsible conduct of activities in the life sciences, which embraces the wider array of issues that the community addresses to fulfil its responsibilities to society. Second, the report¹⁰ acknowledged that the “growing body of research about how individuals learn...and the most effective methods for teaching them” could offer valuable insights into how

education about dual-use issues could best be delivered. In particular, the report underscored that, given the complexities of the social and ethical dimensions of dual use, teaching strategies that encourage reflection and critical thinking could tremendously enhance the effectiveness of biosecurity education and promote its sustainability. The report specifically drew attention to the value of active learning and how, when properly implemented, it enables students to acquire the skills necessary for the practical application of theories and concepts.

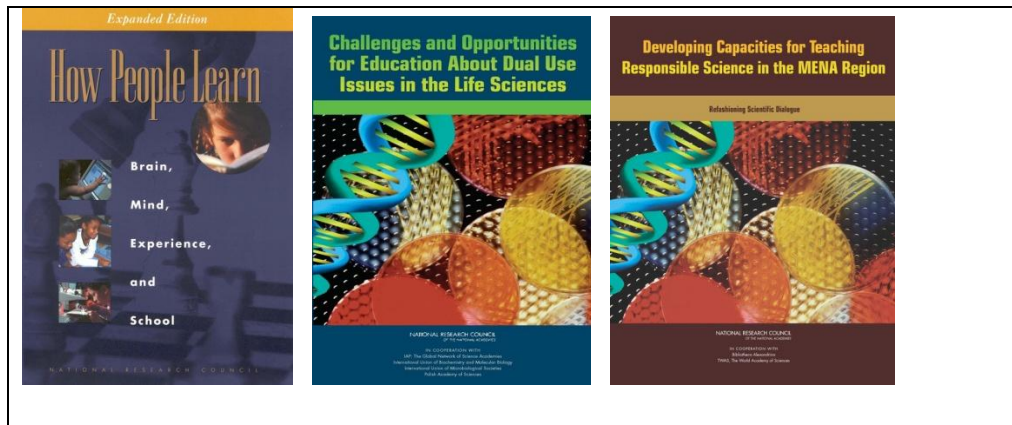
9. A critical component of active learning is that the learner, rather than the instructor, is at the centre and focus of the activities taking place in the classroom. As such, it is a learner-centred mode of instruction that stresses collaboration, enquiry and critical thinking. Active learning helps people take control of their own learning, by enhancing their abilities to recognise when they understand and when they need more information, thus allowing them to predict their performances on various tasks. Teaching practices congruent with active learning engage learners as active participants in their learning, by focussing their attention on critical elements, fostering abstraction of common themes or procedures (principles), and evaluating their own progress toward understanding.¹¹ Sense-making, self-assessment, and reflection on what worked and what needs improving, are thus crucial elements of the active learning approach.

10. The US NAS report¹² How People Learn: Brain, Mind, Experience, and School, which appeared in 2000 (see Box 20.4), provided an extensive overview of the value and practical uses of teaching approaches that encourage active learning. The report showed that there is a substantial body of evidence that active learning approaches enhance learning generally, enabling students to transfer and extend what they have learnt in one context to new contexts. In addition, active learning strategies for instruction “have been shown to increase the degree to which students will transfer to new situations without the need for explicit prompting.” Overall, the report¹³ strongly endorsed the benefits of active learning strategies, underscoring that the:

Integration of [active learning] instruction with discipline-based learning can enhance student achievement and develop in students the ability to learn

independently. It should be consciously incorporated into curricula across disciplines and age levels.

Box 20.4: Key US NAS Reports on active learning



11. Four essential elements contribute to the proven effectiveness of TBL: those are teams, accountability, immediate feedback, and assignment design.¹⁴

12. TBL is not about groups; it is about teams. Student teams need to be formed by the instructor to ensure maximum diversity, and avoid the formation of sub-groups based on already existing relationships among students. To this end, large teams are recommended, featuring 5-7 students. Teams need to be permanent, that is, students are not allowed to change teams for the duration of the course/semester/year.

13. Teams presuppose competitive spirit and accountability. Since team performance depends on the preparation of all members, there is a powerful incentive for students to complete the pre-readings and come ready to class. In this way, peer-pressure and support from co-team members, rather than fear from authority in the face of the instructor, serve as the main driver for changing behaviour in order to demonstrate diligence. Peer-evaluation is crucial in this regard, and needs to be counted toward the formal assessment.

14. Providing students with immediate feedback is important for both self- and team-evaluation. It allows students to assess their performance and reflect on their strengths and weaknesses, both as individuals and as a team, and to determine in which areas

they do well and which aspects require improvement, thus encouraging them to assume ownership of, and responsibility for, their own learning.

15. In order to ensure that students achieve the learning outcomes set at the start of the class, assignment design is critical. To this end, the application exercises need to combine team decision-making on complex issues and reporting in a simple form. Presenting students with complex problems encourages them to think critically and form arguments, using key concepts discussed in class. At the same time, using a simple format for reporting (e.g. multiple choice, practical task) ensures focused discussion and maximum involvement of the whole team.

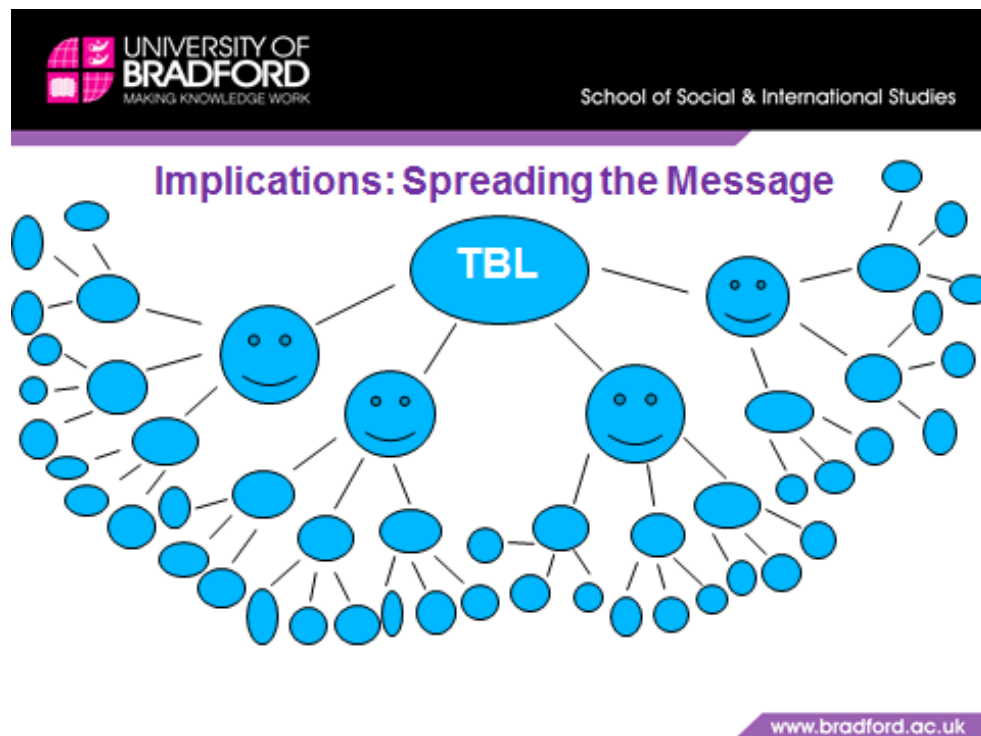
Implications and conclusions

16. As the analysis of the seminar results presented in the previous section vividly demonstrates, Team-Based Learning is an efficient and effective technique for teaching biosecurity to university students, both at undergraduate and post-graduate level. The pre-reading exercise allows students to develop at least a basic grasp of the issues to be discussed in class, which in turn enhances their capacity for active engagement with the knowledge application tasks. Given the interactive nature of the format, students can take full ownership of the learning process, evaluate their performance, and monitor their progress. Thanks to the application exercises, they are encouraged to apply the theories and concepts learned during the pre-reading and the individual and team Readiness Assurance Tests (iRATS and tRATs) in practice, and thus acquire transferable skills necessary for their professional practice. Moreover, students' positive feedback further reinforces the value of team-based learning as an innovative, interactive and effective way of enhancing students' understanding of complex concepts. The format encourages critical thinking, reflection and collaborative work, by giving students the unique opportunity to articulate and examine their own reasoning, and explore a variety of different perspectives in search for an optimal solution.

17. Team-Based Learning is designed to assist both instructors and learners, as they begin to engage with various subject matter. It is a particularly useful teaching approach as far as biosecurity is concerned, since it helps learners to overcome the

inherent divide between the ‘hard’ and ‘soft’ sciences, and engage in critical reflection and deliberation on ethical, legal, and social issues. Evidence has shown that the format is easy to replicate without extensive prior training, provided that relevant teaching resources are made available (Figure 20.3). Furthermore, TBL could be used with various audiences at different level of instruction, in different contexts, with great effectiveness. Combining adequate educational content with a proven delivery technique, that can be applied in various teaching settings and contexts, could have a tremendous impact on engaging prospective life scientists at an early age with the ethical, social and legal implications of their work. It also could be seen as an important step toward fostering a culture of responsibility in the life sciences, which would ensure that any attempt at misuse of related knowledge and materials is effectively discouraged, and would help to guarantee that biotechnology is utilised only for peaceful, prophylactic and protective purposes, as required by the BTWC.

Figure 20.3: The benefits of Team-Based Learning as a train-the-trainer methodology



References

¹ Special thanks to Mrs Rebecca McCarter, Learning and Teaching Development Officer at the School of Life Sciences, University of Bradford for the guidance and logistical support she provided during the organisation and facilitation of the Seminar.

² See <http://www.edpsycinteractive.org/topics/cognition/bloom.html> (accessed 30 June 2015).

³ The emphasis laid on the scientists' lack of awareness is a hypothetical element added for the purpose of provoking discussion. In reality, the lead Dutch scientist, Dr Ron Fouchier, has been involved in the discussions on dual-use research in the Netherlands for a long time. He was also part of the focus group worked on the Royal Dutch Academy of Sciences' Code of Conduct on Biosecurity.

⁴ See <http://tblc.roundtablelive.org/Resources/Documents/TBL%20Handout%20Aug%2016-print%20ready%20no%20branding.pdf> (accessed 20 March 2015).

⁵ A Team-Based Learning seminar on biosecurity and dual-use issues was held in May 2014 in Rabat, Morocco. The seminar titled *Team-Based Learning Seminar on Dual Use and Biosecurity* was part of the EU CBRN Centres of Excellence Project 18: 'International Network of Universities and Institutes for Raising Awareness on Dual-Use Concerns in Biotechnology' seminar series coordinated by the Landau Network-Centro Volta in Italy. Thirty-seven doctoral students across various Moroccan universities took part in the two-day event. See <http://landaunetwork.org/index.php/2014/05/eu-cbrn-coe-project-18-workshop-at-the-university-mohammed-v-rabat-agdal-2/> (accessed 30 June 2015).

⁶ Thanks to Giulio Mancini for the data analysis in Figure 4.2 and 4.3, and Box 4.5.

⁷ In June 2012 the University Delft held a Seminar on '*Biosecurity: Designing a Web of Prevention*', which combined lectures with practical workshop, as part of which students were divided into small groups and asked to design a 'web of prevention' to prevent the hostile misuse of the life sciences. The seminar was conducted within the framework of the EUBARnet Project, coordinated by the Landau Network-Centro Volta. Further information about the seminar is available at http://www.eubarnet.eu/?post_type=seminar&p=472 (accessed 30 June 2015).

⁸ Committee on Education on Dual Use Issues in the Life Sciences, National Research Council, *Challenges and Opportunities for Education about Dual Use Issues in the Life Sciences*, The National Academies Press, 2010, available at http://www.nap.edu/catalog.php?record_id=12958 (accessed 30 June 2015).

⁹ Ibid.

¹⁰ Ibid.

¹¹ Committee on Developments in the Science of Learning with additional material from the Committee on Learning Research and Educational Practice, National Research Council, *How People Learn: Brain, Mind, Experience, and School* (expanded version), The National Academies Press, Washington, 2000, available at <http://www.nap.edu/openbook.php?isbn=0309070368> (accessed 30 June 2015).

¹² Ibid.

¹³ Ibid.

¹⁴ Larry Michaelson et al., 'Team-Based Learning: Small Group's Learning's Next Big Step', *New Directions in Teaching and Learning*, 116 (2009).

Chapter 21: Conclusion

Tatyana Novosiolova and Simon Whitby

Strengthening biological security and building the web of prevention

1. At the BTWC Meeting of Experts in August 2015, Dr Cédric Invernizzi of SPIEZ Laboratory in Switzerland gave a presentation titled, “CRISPR/Cas: An Adaptive Bacterial Immune System on Its Way to Become a Game Changer in Genetic Engineering”.¹ This presentation highlighted the potential benefits and risks associated with the CRISPR/Cas technique (see Chapter 3). Referring to a number of papers that have already been published in the scientific literature, he provided an example of the potential benefit of using CRISPR/Cas as a gene editing tool “to wipe out disease-carrying mosquitoes or ticks, eliminate invasive plants or eradicate herbicide resistance”.² At the same time, he drew attention to the concerns that have been voiced within the scientific community regarding the technique. For example, according to George Church, a bioengineer at Harvard Medical School, there is “a risk of irreversibility – and unintended or hard-to-calculate consequences for other species”.³ He and other like-minded scientists see “a clear warning that the democratisation of genome editing through CRISPR could have unexpected and undesirable outcomes”. Such concerns are hardly ill-founded, given the enormous potential of the technique and the fact that, “unlike other gene-editing methods, it is cheap, quick and easy to use”. As one commentator has noted, “this power is so easily accessible by labs – you don’t need a very expensive piece of equipment and people don’t need to get many years of training to do this”.⁴

2. The increasing availability, accessibility and democratisation of CRISPR/Cas is important, not least because it echoes Matthew Meselson’s prediction (see Chapter 3) that “as our ability to modify fundamental life processes continues its rapid advance, we will be able not only to devise additional ways to destroy life but will also become able to manipulate it – including the processes of cognition, development, reproduction, and inheritance. A world in which these capabilities are widely employed for hostile purposes would be a world in which the very nature of conflict

had radically changed. Therein could lie unprecedented opportunities for violence, coercion, repression, or subjugation.”⁵

3. Against the backdrop of rapid scientific and technological advancement in the 21st century, and intensive global diffusion of expertise across different disciplines, raising awareness among those engaged in the life sciences is essential for building an effective web of prevention. The joint policy statement of three major UK life science research funding bodies – the Wellcome Trust, Biotechnology and Biological Sciences Research Council (BBSRC), and the Medical Research Council (MRC) – on “Managing Risks of Research Misuse”, released in July 2015, has a similar message: “We believe that a system based primarily upon self-governance by the scientific community, but drawing on the inputs of other key stakeholders, will ultimately provide the most effective means of managing risks of misuse. We suggest that the community, of which we as funders are part, should take active steps to further develop mechanisms of self-governance, and that through doing so the community can ensure that responsibly conducted research is not unnecessarily obstructed. Crucially, this process must be underpinned by an active ongoing dialogue between researchers and other key stakeholders, including Governments and security services.”⁶

The role of scientists in promoting and strengthening biological security

4. In 2009 the Global Partnership Working Group (see Chapter 7) issued a document titled “Recommendations for a Coordinated Approach in the Field of Global Weapons of Mass Destruction Knowledge Proliferation and Scientist Engagement”,⁷ drawing attention to the fact that:

“Closer attention is now needed to engaging scientists and raising awareness and responsibility among them, to prevent their knowledge in legitimate scientific disciplines to be diverted for unintended malicious purposes, and to strengthen frameworks within which to prevent the spread of sensitive information and to promote collaborations to advance common non-proliferation objectives.”

And that

“Chemical, biological, radiological and nuclear research and applications are receiving growing attention in this perspective. Education and training are becoming increasingly important, notably in areas where the knowledge and expertise are rapidly advancing.” (Emphasis added)

5. A fundamental point in the Working Group’s “Recommendations” is the recognition that scientists are seen as part of the solution to the problem of preventing potential security threats, and that their active participation in the development and implementation of relevant biological security measures, policies and approaches is a vital ingredient for maximising their effectiveness and achieving sustainability.⁸ The chapters throughout this book have aimed to illustrate both the need for a broad engagement by life science communities, and the multiple different ways in which scientists can contribute to the goal of promoting and strengthening biological security globally, and building an effective web of prevention.

- i. The emerging security challenges and potential risks arising from the rapid development of biotechnology and natural disease outbreaks (Chapter 2, 3, 4 and 5) require that the existing international biological security regime (Chapter 6 and 7) is adapted to the changing security landscape, through a broad and effective multi-stakeholder engagement among all relevant parties concerned, especially, but not exclusively, life scientists.
- ii. Dialogue between the life science and security communities (Chapter 8), including national and international law enforcement agencies (Chapter 12 and 13), is critical to ensure that appropriate and timely risk assessment is conducted, and that adequate steps and mechanisms are put in place for the prevention of, and response to, possible biological security concerns.
- iii. Domestic and international scientific organisations (Chapter 10) can serve as important vehicles for channelling relevant expert advice and putting forward policy proposals, something evident in the partnership between National Science Academies and the BTWC ISU, and the participation of scientists in the BTWC Meetings in Geneva (Chapter 11).

- iv. The biotechnology industry and local, regional, and international biosafety associations, too, constitute important partners in strengthening the international biosecurity regime (Chapter 9 and 5).
- v. National implementation measures can also benefit significantly from a broader engagement with life scientists in different ways, which should be appropriate to individual states' priorities, culture and local context (Chapter 14, 15, 16, and 17).
- vi. It is difficult to overstate the contribution which life science communities can make to enhancing biological security globally (Chapter 18); it remains of paramount importance to increase awareness among those in the life sciences of their responsibilities, especially in light of the novel security concerns arising from the progress of science and technology; this requires attention and effective action (Chapter 19 and 20).

6. Building an integrated web of prevention requires that relevant action with regard to the prevention of biological threats is taken at all levels: from the individual to the international. There are no 'silver bullets' and 'quick fixes'. Rather, this is a long-term endeavour, in which all relevant stakeholders – including scientists, industry, publishers, funders, law enforcement agencies, governments and the public – need to be actively involved and partner together. The examples presented in the preceding chapters are indicative and not prescriptive, as one size does not fit all. They highlight, above all, that efforts to foster a biological security culture need to be context-specific, taking into account local contingencies, priorities, and realities. Relevant policies, measures and guidelines need to be developed in close collaboration with all concerned parties, to ensure a balanced approach to the prevention of risks, without stifling innovation and research for peaceful ends. Continuous dialogue among stakeholders and multisectoral coordination at national, regional and international level are critical, for both the effective implementation and sustainability of biological security mechanisms and practices.

Looking ahead: international biological security education and outreach

7. The need for biological security education has been widely acknowledged, and there seems to be a growing consensus that increased awareness among life scientists of the potential security implications of their work could help strengthen the international biosecurity regime and build the web of prevention, by ensuring that the knowledge, materials, and products generated by scientific and technical advances in the life sciences are used solely for prophylactic, protective, or other peaceful purposes. A similar trend is observed in other areas of disarmament and non-proliferation, such as nuclear and chemical security. For instance, in 2010 an International Nuclear Security Education Network was established under the auspices of the International Atomic Energy Agency. The network comprises more than 130 member institutions, and has played a leading role in promoting nuclear security education through the development of training resources, strengthening faculty capacities, and reaching out to universities and other relevant organisations.⁹

8. Chemical security education has been gaining in momentum as well. For instance, at its Eightieth Session held in October 2015, the Executive Council of the OPCW passed a decision recommending “the establishment of an Advisory Board on Education and Outreach”.¹⁰ This decision was subsequently approved at the 20th Session of the Conference of States Parties to the CWC. The publication of The Hague Ethical Guidelines in September 2015 is another important milestone in the process of raising awareness of the CWC among those engaged in the chemical sciences.¹¹ The guidelines are designed to serve as a useful framework for debating ethical issues in relation to chemical disarmament and non-proliferation and, as such, could be seen as core elements for the development of ethical codes.¹²

9. The nuclear and chemical security education experiences highlight the critical importance of international cooperation and high-level coordination for the implementation of effective, efficient and sustainable awareness-raising measures. A comprehensive approach to biological security education, underpinned by multi-stakeholder engagement, a flexible combination of scientist-led ‘bottom-up’ and

government-supported initiatives, adequate financial support, and strategic planning, can significantly contribute to fostering a culture of responsible conduct in the life sciences. The Eighth Review Conference of the BTWC in 2016 offers a golden opportunity for promoting biological security education and outreach globally. To this end, among its possible outcomes could be an agreement among States Parties on the need to take effective action, both collectively and nationally, to raise awareness and promote engagement by the life science community.

10. In turn, this could lead to the inclusion in a new intersessional programme of a platform for discussion and decision-making on issues related to education and outreach. Closer collaboration with other international organisations and bodies seeking to promote security and disarmament education – for example, the Education and Outreach Advisory Board of the OPCW – could also be of benefit to the goal of engaging life scientists on the broader implications of their work. This book and the supplementary Team-Based Learning handbook could serve as starting points for the development of further relevant education resources, and as vehicles for fostering regional and cross-regional joint initiatives, designed to enable life scientists to engage with the broader issues arising from their work, in an effective and sustainable manner.

References

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- ¹ The presentation is available at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/A60F7B2106175E24C1257E9F0065DDEF/\\$file/Swiss_presentation_BWC_MX_2015_S&T-CRISPR_INC.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/A60F7B2106175E24C1257E9F0065DDEF/$file/Swiss_presentation_BWC_MX_2015_S&T-CRISPR_INC.pdf)(accessed 30/10/2015).
- ² Heidi Ledford, ‘CRISPR, the Disrupter’, *Nature*, vol. 522:7554(2015) pp. 20-24, available at <http://www.nature.com/news/crispr-the-disruptor-1.17673>(accessed 30/10/2015).
- ³ Ibid.
- ⁴ Ibid.
- ⁵ Mathew Meselson, ‘Averting the Hostile Exploitation of Biotechnology’, *CBWCB*, vol.48 (2000), pp.16-19. <http://www.sussex.ac.uk/Units/spru/hsp/documents/Pages%20from%20cbwcb48.pdf>(accessed 30/10/2015).
- ⁶ See Appendix A for a list with additional training resources on biological security and other relevant policy documents, guidenlines, and publications.
- ⁷ G8, *Recommendations for a Coordinated Approach in the Field of Global Weapons of Mass Destruction Knowledge Proliferation and Scientist Engagement*, 2009. See http://www.g8italia2009.it/static/G8_Allegato/Annex_B.2.pdf(accessed 30/20/2015).

⁸ Jo Husbands, *Cooperation on Biosecurity as Part of a Strategy to Prevent the Misuse of the Life Sciences*, paper presented at the International Studies Association Annual Convention, 3-6 April 2013, San Francisco, California, USA.

⁹ Christopher Hobbs, 'Nuclear Security: Promoting Education and Awareness', EU High Level Event on 'International Cooperation to Enhance a Worldwide Nuclear Security Culture', 20 March 2014, Amsterdam. Available at <http://ec.europa.eu/dgs/jrc/downloads/events/20140320-nuclear-security/20140320-nuclear-security-hobbs.pdf> (accessed 30/10/2015).

¹⁰ OPCW Executive Council, *Decision: Establishment of an Advisory Board on Education and Outreach*, EC-80/DEC.5, October 2015, The Hague, The Netherlands, available at <https://www.opcw.org/?id=2555> (accessed 30/10/2015).

¹¹ Full text of The Hague Ethical Guidelines is available at <https://www.opcw.org/special-sections/science-technology/the-hague-ethical-guidelines/> (accessed 30/10/2015).

¹² For background information on The Hague Ethical Guidelines, see <https://www.opcw.org/special-sections/science-technology/the-hague-ethical-guidelines/background-information/> (accessed 30/10/2015).

Glossary

Academy of Science (of South Africa): The national Academy of Science of South Africa that represents the country in the international community of science academies. It was inaugurated by Nelson Mandela in 1996 and has the mission of using science for the benefit of society.

Active Learning: Methods of teaching designed to involve the active participation of students.

Ad Hoc Group (AHG): A term agreed by the States Parties to the BTWC for the group mandated to consider measures to strengthen the Convention, including measures to promote compliance. The AHG held 24 meetings between January 1995 and July/August 2001.

Aerosol: Particles or droplets suspended in air.

Asilomar Conference: A scientific conference held in California in 1975 to review scientific progress in research on genetic engineering technologies (recombinant DNA technologies), which were starting to become a practical possibility, and to discuss the associated potential biohazards. It recommended principles to address the potential biohazards, through matching appropriate containment with assessed risks.

Australia Group: An informal forum established in 1985 and now consisting of 41 countries plus the European Union (as of June 2015), which cooperate in their efforts to prevent exports of materials and technology from contributing to the proliferation of chemical and biological weapons (CBW) through the coordination of national export measures.

Avian Influenza: An infectious viral disease of birds, commonly called bird flu.

Bacteria: Microscopic, single-celled organisms belonging to Kingdom Monera that possess a prokaryotic type cell structure, which means their cells are not compartmentalised and their DNA can be found throughout the cytoplasm rather than within a membrane bounded nucleus.

Bioethics: The application of ethics to the science and practice of biology.

Biological agent: considered in this book to be any biological substance that can be used to cause death, incapacitation or other harm to humans and animals, and/or damage to plants. This definition includes not only microorganisms and toxins, but also bioregulators.

Biological and Toxin Weapons Convention (BTWC): The international agreement that was negotiated between 1969 and 1971, was opened for signature in 1972 and entered into force in 1975, that adds a series of further prohibitions (on the development, production and stockpiling of biological and toxin weapons) to the ban on the use of biological weapons embodied in the 1925 Geneva Protocol. Also known as the Biological Weapons Convention (BWC).

Biological Weapon: A biological agent intended to be used for hostile purposes.

Biopreparat: The organisation that provided a 'civilian' cover for the offensive biological weapons programme of the former Soviet Union. There was also a part of the programme run by the Ministry of Defence.

Bioregulator: A chemical that regulates physiological processes within an organism.

Biorisk Spectrum: A concept in which the threat from biological agents is envisaged to lie on a spectrum, ranging from natural disease events on one end, through events with an accidental origin, or negligence, to efforts to cause deliberate harm.

Biological Safety (Biosafety): Principles, technologies, practices and measures implemented to prevent accidental release of, or unintentional exposure to, biological agents.

Biological Security (Biosecurity): As discussed in Chapter One this term can have different meanings in different contexts. As used here, Biosecurity can be divided into Laboratory/Facility Biosecurity and wider Dual-Use Biosecurity. Laboratory Biosecurity consists of protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and related resources, as well as unauthorised access to, retention or transfer of such material.

Wider Dual-Use Biosecurity consists of measures such as oversight of research, codes of conduct and education requirements designed to ensure that the results of benign research are not misused for malign purposes.

Biosecurity Champions: Prominent scientists who take an active role in promoting biosecurity, for example Professors David Relman (Box 2.4) and Matthew Meselson (Box 3.1).

Biotechnology: Biotechnology is defined as the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

Bioterrorism: The threat or hostile use of biological or toxin agents for ideological or political purposes.

Bioterrorism Incident and Response Guide: The guide produced by INTERPOL to guide responders having to deal with bioterrorism incidents.

Bottom-Up Measures: Measures developed and implemented by people actively involved, rather than imposed by authorities through legislation or regulation - for example in biosecurity education.

CBRN: Chemical, Biological, Radiological, Nuclear.

Chemical Weapons Convention (CWC): The international agreement negotiated between 1984 and 1992, which was signed in 1993 and entered into force in 1997, that totally prohibits the development, production, stockpiling and use of chemical weapons; and requires their destruction.

Chemical Weapons Convention Schedules: The lists of chemicals that are used for the application of routine verification measures, as specified in the Convention.

Chemical Weapon: According to Article II.1. of the CWC, "chemical weapons" means the following, together or separately:

- (a) Toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as the types and quantities are consistent with such purposes;
- (b) Munitions and devices, specifically designed to cause death or other harm through the toxic properties of those toxic chemicals specified in subparagraph (a), which would be released as a result of the employment of such munitions and devices;
- (c) Any equipment specifically designed for use directly in connection with the employment of munitions and devices specified in subparagraph (b).

Codes of Conduct (for Life Scientists): Codes of Conduct for life scientists can be of three different types: Aspirational Codes, Codes of Conduct and Codes of Practice. Aspirational Codes

suggest ideal forms of behaviour, but have no enforcement measures. Codes of Conduct give guidance as to correct practice, and non-observance can have consequences for a practitioner. Codes of Practice are likely to be backed up by legal sanctions for non-observance. Thus, discussion of Codes of Conduct can be confusing unless these differences are understood.

Compliance Assurance: Means by which compliance of a State with its obligations to an international agreement can be assured in the view of other States Parties.

Convention on Biological Diversity (CBD): CBD is an international agreement that entered into force in 1993. It has three main objectives: the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits arising from the use of genetic resources.

Convergence of Chemistry and Biology: The view that, at least in some aspects, chemistry and biology are increasingly overlapping, for example in the field of molecular biology, or in the chemical synthesis of biological material and the biosynthesis of chemical materials.

Defoliant: A chemical spray or dust applied to plants in order to cause the leaves to drop off prematurely; defoliants have been used to remove cover from an enemy in warfare.

Do It Yourself (DIY) BIO: The DIY BIO Organisation was founded in 2008, with the mission of establishing a vibrant, productive and safe community of ‘do-it-yourself’ biologists.

Disease Outbreak: A disease outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season. An outbreak may occur in a restricted geographical area or may extend over several countries.

Dual-Use Research: Research yielding new technologies or information with the potential for both benevolent and malevolent applications.

Dual-Use Research of Concern (DURC): Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Dual-Use Technology: Technology normally used for civilian purposes, but which may have military applications, or may contribute to the proliferation of weapons of mass destruction.

Ebola Virus Disease (EVD): Ebola Virus Disease, also known as Ebola haemorrhagic fever, is a rare and deadly disease caused by infection with one of the Ebola virus strains. The Ebola virus can cause disease in humans and non-human primates (monkeys, gorillas, and chimpanzees). Ebola is caused by infection with a virus of the family *Filoviridae*, genus *Ebola virus*. There are five identified Ebola virus species, four of which are known to cause disease in humans.

Fink Committee Report: This report of a committee chaired by Gerald Fink, titled *Biotechnology Research in an Age of Terrorism*, was published by the United States National Academies in 2003, and has been influential in the debates on dual-use research since then.

Food and Agriculture Organization (FAO): The Food and Agriculture Organization of the United Nations leads efforts to improve agriculture, forestry and fishing around the world.

Gain-of-Function (GOF) Experiments: Experiments designed to furnish organisms with new traits, whether good or harmful. In the context of biosafety/biosecurity debates in connection with studies, particularly on influenza viruses, it has often been used to refer to experiments to increase the transmissibility and or the pathogenicity of potential pandemic pathogens.

1925 Geneva Protocol: The international agreement concluded in 1925, originally intended as part of a more far reaching disarmament proposal, that now forms part of customary international law, and bans the use of chemical and biological weapons.

Global Partnership (Against the Spread of Weapons and Materials of Mass Destruction): A security initiative launched at the 2002 G8 summit, designed to prevent terrorists and those that harbour them from acquiring and using weapons and materials of mass destruction. The initiative was extended in 2011, with a focus on nuclear security, biological security, engagement with scientists, and the implementation of United Nations Security Council Resolution (UNSCR) 1540. The Global Partnership had 30 members as of June 2015.

H5N1 Influenza Virus: A highly pathogenic avian (bird) flu virus. It does not usually infect humans, but can be infectious and highly pathogenic to people who have contact with infected birds.

iClicker: A device that allows students to indicate their choices in Team Based Learning exercises, so that the instructor can monitor the choices made on a central computer.

Individual Readiness Assurance Test (iRAT): Initial individual test carried out in a Team Based Learning exercise to assess the level of understanding of individual students.

iGEM Competition: A worldwide synthetic biology competition, initially aimed at university undergraduates, but now much extended to include, for example, high school and graduate students.

Implementation Support Unit (ISU): This institutional support for the Biological and Toxin Weapons Convention was created by the Sixth Review Conference in 2006. The unit provides support and assistance for administrative matters, national implementation, Confidence-Building Measures and universality. In 2011, the Seventh Review Conference renewed its mandate, and expanded it to include the establishment and administration of the Assistance and Cooperation Database. It is based in the United Nations Office for Disarmament Affairs in Geneva, Switzerland.

Insider Threat: A person with authorised access, who uses that access, wittingly or unwittingly, to harm national security interests or national security through unauthorised disclosure, data modification, espionage, terrorism, or kinetic actions, resulting in loss or degradation of resources or capabilities.

InterAcademy Panel (IAP): The IAP is the global network of national scientific academies.

International Committee of the Red Cross (ICRC): The ICRC is part of the International Red Cross and Red Crescent Movement, and is based in Geneva, Switzerland. It works to ensure humanitarian protection and assistance for victims of war and other violent situations.

International Council for the Life Sciences (ICLS): ICLS is a non-profit, non-partisan organisation dedicated to enhancing global biological security and safety.

International Federation of Biosafety Associations (IFBA): IFBA is the global association of national biosafety professionals.

International Governance (of Biotechnology): Covers the whole set of international agreements that have been developed to govern the growth of the capacity of biotechnology. These agreements cover, for example, environmental, safety, drug control and arms control issues.

International Health Regulations (IHR) 2005: The IHR are legally binding international regulations agreed in 2005 by all World Health Organization Member States, designed 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.

INTERPOL: Is the largest international police organisation. Its role is to enable police around the world to work together.

Intersessional programme (ISP): Programme of annual meetings of the Biological and Toxin Weapons Convention States Parties held between Review Conferences since the reconvened Fifth Review Conference in 2002; focused on discussing and promoting common understandings and effective action on specific topics, to strengthen the implementation of the Convention. The ISPs thus far have been 2003-2005; 2007-2010; 2012-2015.

Lemon-Relman Committee Report: A report titled *Globalization, Biosecurity and the Future of the Life Sciences* produced in 2006 by a committee of the US National Academies, chaired by Stanley Lemon and David Relman. This report built on the report of the Fink Committee and is

significant particularly for its emphasis on the need to consider a much wider range of dual-use aspects of the life sciences than just microbiology.

Meeting of Experts (of the BTWC) (MXP): This is the first of the two meetings held on an annual basis under the current intersessional programme of the Biological and Toxin Weapons Convention. Generally held in the summer in Geneva, it deliberates on the issues identified by the Review Conferences for consideration. The Chairman produces a synthesis paper after the meeting that seeks to reflect the views, comments and observations made by the States Parties and other participants. This helps inform discussions at the Meeting of States Parties – see below.

Meeting of States Parties (of the BTWC) (MSP): The second of the two meetings held on an annual basis under the current Intersessional Programme of the Biological and Toxin Weapons Convention. Held towards the end of the year, it considers the work of the Meeting of Experts and identifies, where possible, common understandings and effective actions on the issues identified by the Review Conferences for consideration. Conclusions and results are reached by consensus, for action by States Parties or consideration by the next Review Conference.

MERS: Middle East Respiratory Syndrome (MERS) is a respiratory illness caused by a coronavirus (MERS-CoV) that is new to humans. It was first reported in Saudi Arabia in 2012.

Middle East Scientific Institute for Security (MESIS): MESIS is an independent Jordanian non-governmental organisation, based in Amman and associated with the Royal Scientific Society.

National Implementation Measures (of the BTWC): The mechanisms put in place by a State Party to prohibit and prevent the development, production, stockpiling, acquisition, or retention of biological agents, toxins, weapons, equipment and means of delivery (as specified in Article I of the Convention) within its territory, under its jurisdiction or under its control anywhere. They include relevant legislative, regulatory and administrative frameworks, and methods for their enforcement.

National Science Advisory Board for Biosecurity (NSABB): The NSABB is a federal advisory committee that addresses issues related to biosecurity and dual-use research at the request of the US Government.

Non-Lethal Weapons: Weapons intended to cause temporary incapacitation rather than to kill.

Nuclear Non-Proliferation Treaty (NPT): The international agreement negotiated between 1965 and 1968, that entered into force in 1970 and prohibits the proliferation of nuclear weapons.

Nuclear Weapon: A nuclear explosive device used for hostile purposes.

OIE: The intergovernmental organisation responsible for improving animal health worldwide. In May 2003 the Office International des Epizooties became the World Organisation for Animal Health, but kept its historical acronym OIE.

Operation S³OMMET: Is a project of the Chemical, Biological, Radiological, Nuclear and Explosives (CBRNE) Sub-Directorate of INTERPOL. Its aim is to enhance the safety and security of biological materials in regions where this is most needed.

Organisation for the Prohibition of Chemical Weapons (OPCW): The international organisation located in The Hague, that oversees the implementation of the Chemical Weapons Convention.

Oversight Systems (for Experiments): Policies that aim to preserve the benefits of life sciences research, while minimising the risk of misuse of the knowledge, information, products, or technologies provided by such research.

Pedagogy: The method and practice of teaching.

Potential Pandemic Pathogens (PPPs): PPPs are pathogens that are potentially highly contagious, potentially highly deadly, and not currently present in the human population.

Princess Haya Biotechnology Centre (PHBA): The PHBA was established at the Jordan University of Science and Technology in 2005. It houses 16 research laboratories and supports science at the national and regional levels.

Project Coast: The South African chemical and biological weapons programme of the 1980s and early 1990s.

Pugwash Conferences on Science and World Affairs: Pugwash is an international organisation that brings together scholars and public figures to work towards reducing the dangers of armed conflict. It was founded in 1957 in Pugwash, Nova Scotia, Canada. Pugwash and its co-founder Sir Joseph Rotblat were awarded the Nobel Peace Prize in 1995.

Recombinant DNA Techniques (rDNA): Methods of joining together DNA molecules from more than one organism, and inserting them into a host organism to produce new genetic combinations.

Responsible Conduct of Research (RCR): Research carried out in compliance with widely accepted high standards dealing with, for example, authorship, conflict of interests, data management, plagiarism, and human and animal subjects.

Review Conferences (of the BTWC): The conferences of States Parties, usually held on a five yearly basis, to review the operation of the Biological and Toxin Weapons Convention, with a view to assuring that the purposes of its preamble and its provisions are being realised. Such reviews also take into account any new scientific and technological developments relevant to the Convention.

Robert Koch Institute (RKI): RKI was founded originally by Robert Koch in 1891. It is now part of the German Federal Government, and has responsibility for disease prevention and control.

Royal Scientific Society (RSS): RSS is the largest applied research institution, consultancy and technical support service provider in Jordan, and a regional leader in science and technology.

Sandia National Laboratories: Sandia National Laboratories is managed by Sandia Corporation, a subsidiary of Lockheed Martin Corporation. It works as a contractor for the US Department of Energy's National Nuclear Security Administration.

SARS: Severe acute respiratory syndrome (SARS) is caused by a corona virus (SARS CoV), which was first identified in 2003. It causes serious pneumonia.

Scientific Advisory Board (of the OPCW): The group of independent experts appointed by the Director General of the OPCW to provide him with advice on scientific and technological developments.

Scientific Misconduct: Is the violation of widely accepted standards of scientific and ethical conduct, such as the fabrication or falsification of data, or plagiarism in research or reporting of results.

Security Council Resolution 1540: A United Nations Security Council resolution, adopted on 28 April 2004, obliging States to: i) refrain from supporting non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their delivery systems; ii) adopt and enforce appropriate and effective laws prohibiting activities involving the proliferation of such weapons and their means of delivery to non-State actors, in particular for terrorist purposes; and iii) implement and enforce appropriate controls over related materials in order to account for and secure items in production, use, storage or transport; physically protect such materials; detect, deter, prevent and combat the illicit trafficking and brokering in such items, through effective border controls and law enforcement efforts; control the export, transit, trans-shipment and re-export of such items, and the provision of funds and services related to such export and trans-shipment that would contribute to proliferation; and penalise violations.

Statens Serum Institut (SSI): A research institute under the Danish Ministry of Health, which deals with the prevention of infectious diseases and biological threats.

Synthetic Biology: The synthesis of complex, biologically based (or inspired) systems, which display functions that do not exist in nature. This engineering perspective may be applied at all

levels of the hierarchy of biological structures – from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of ‘biological systems’ in a rational and systematic way.

Tacit Knowledge: Knowledge that cannot be conveyed by written or spoken language, but which involves a process of learning by example, or by doing, that can only be acquired through practical hands-on experience.

Team Based Learning (TBL): A form of active learning that involves teams of students.

Team Readiness Assurance Test (tRAT): Test carried out after the iRAT in a TBL exercise to assess the level of understanding of the team as a whole.

Threat Spectrum: A concept in which the threat from chemical and biological agents is envisaged to lie on a spectrum ranging from classical chemical weapons, through mid-spectrum agents (such as toxins and bioregulators), to traditional and genetically-modified biological agents.

Top-Down Measures: Measures, such as legislation or regulation, developed by higher authorities, and applied to lower levels, for example governmental export controls that have to be implemented by companies.

Toxin: Non-living, poisonous substance produced by many types of living organisms, including animals, plants and bacteria. Toxins cannot reproduce themselves, and therefore cannot produce transmissible diseases; they only affect those individuals that have been directly exposed to them.

Universal Declaration of Human Rights: The Declaration adopted by the UN General Assembly in 1948, which arose out of the experience of the Second World War, and was the first formulation of the rights to which all human beings are inherently entitled.

VEREX: A group established by States Parties to the BTWC at the Third Review Conference in 1991, and which held four meetings between 1992 and 1993 to discuss the pros and cons of possible measures for the verification of the Convention.

Virus: A virus is a small infectious agent that replicates only inside the living cells of other organisms. Viruses can infect all types of life forms, from animals and plants to microorganisms, including bacteria and archaea.

Web of Prevention: The concept of a set of integrated policies, such as export controls and the effective national implementation of the BTWC and CWC, that together minimise the possibility that biology and chemistry will be misused by those with hostile intent.

World Health Organization (WHO): The WHO is the directing and coordinating authority for international health within the United Nations system.

