

Governance of Dual Use Research in the Life Sciences

ADVANCING GLOBAL CONSENSUS ON RESEARCH OVERSIGHT

PROCEEDINGS OF A WORKSHOP

James Reville, Jo Husbands, and Katherine Bowman, *Rapporteurs*

Board on Life Sciences
Division on Earth and Life Studies

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

In Collaboration with

InterAcademy Partnership
Croatian Academy of Sciences and Arts
Croatian Society for Biosafety and Biosecurity

THE NATIONAL ACADEMIES PRESS

Washington, DC

www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, NW Washington, DC 20001

This activity was supported by Grant No. 2017-170331 (5384) from the Open Philanthropy Project, a donor advised fund of the Silicon Valley Community Foundation. Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

International Standard Book Number-13: 978-0-309-47799-4

International Standard Book Number-10: 0-309-47799-9

Digital Object Identifier: <https://doi.org/10.17226/25154>

Additional copies of this publication are available for sale from the National Academies Press, 500 Fifth Street, NW, Keck 360, Washington, DC 20001; (800) 624-6242 or (202) 334-3313; <http://www.nap.edu>.

Copyright 2018 by the National Academy of Sciences. All rights reserved.

Printed in the United States of America

Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2018. *Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight: Proceedings of a Workshop*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/25154>.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

The **National Academy of Sciences** was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. Members are elected by their peers for outstanding contributions to research. Dr. Marcia McNutt is president.

The **National Academy of Engineering** was established in 1964 under the charter of the National Academy of Sciences to bring the practices of engineering to advising the nation. Members are elected by their peers for extraordinary contributions to engineering. Dr. C. D. Mote, Jr., is president.

The **National Academy of Medicine** (formerly the Institute of Medicine) was established in 1970 under the charter of the National Academy of Sciences to advise the nation on medical and health issues. Members are elected by their peers for distinguished contributions to medicine and health. Dr. Victor J. Dzau is president.

The three Academies work together as the **National Academies of Sciences, Engineering, and Medicine** to provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

Learn more about the National Academies of Sciences, Engineering, and Medicine at www.nationalacademies.org.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Consensus Study Reports published by the National Academies of Sciences, Engineering, and Medicine document the evidence-based consensus on the study's statement of task by an authoring committee of experts. Reports typically include findings, conclusions, and recommendations based on information gathered by the committee and the committee's deliberations. Each report has been subjected to a rigorous and independent peer-review process and it represents the position of the National Academies on the statement of task.

Proceedings published by the National Academies of Sciences, Engineering, and Medicine chronicle the presentations and discussions at a workshop, symposium, or other event convened by the National Academies. The statements and opinions contained in proceedings are those of the participants and are not endorsed by other participants, the planning committee, or the National Academies.

For information about other products and activities of the National Academies, please visit www.nationalacademies.org/about/whatwedo.

**COMMITTEE ON GOVERNANCE OF DUAL USE
RESEARCH IN THE LIFE SCIENCES: ADVANCING
GLOBAL CONSENSUS ON RESEARCH OVERSIGHT**

Members

SUE MEEK (*Chair*), The Australian National University, Australia
R. ALTA CHARO, University of Wisconsin–Madison, USA
BARUCH FISCHHOFF, Carnegie Mellon University, USA
MICHELE GARFINKEL, EMBO, Germany
ALEXANDER KAGANSKY, Far Eastern Federal University, Russia
ALEMKA MARKOTIĆ, University Hospital for Infectious Diseases
Zagreb, Catholic University of Croatia, and Medical Faculty,
University of Rijeka, Croatia
M. IQBAL PARKER, University of Cape Town, South Africa
ALEJANDRA G. SUÁREZ, Universidad Nacional de Rosario,
Argentina
HERAWATI SUDOYO, Eijkman Institute for Molecular Biology,
Indonesia

Staff

KATHERINE BOWMAN, Senior Program Officer, Board on Life
Sciences
JO L. HUSBANDS, Senior Scholar, Board on Life Sciences
AANIKA SENN, Senior Program Assistant, Board on Life Sciences
TRACY KAMBARA, Mirzayan Fellow, Board on Life Sciences (Spring
2018)
FRANCES SHARPLES, Director, Board on Life Sciences

BOARD ON LIFE SCIENCES

Chair

JAMES P. COLLINS, Arizona State University

Members

A. ALONSO AGUIRRE, George Mason University
ENRIQUETA C. BOND, Burroughs Wellcome Fund
DOMINIQUE BROSSARD, University of Wisconsin–Madison
ROGER D. CONE, University of Michigan
NANCY D. CONNELL, Rutgers New Jersey Medical School
SEAN M. DECATUR, Kenyon College
JOSEPH R. ECKER, Salk Institute for Biological Studies
SCOTT V. EDWARDS, Harvard University
GERALD EPSTEIN, National Defense University
ROBERT J. FULL, University of California, Berkeley
ELIZABETH HEITMAN, Vanderbilt University Medical Center
JUDITH KIMBLE, University of Wisconsin–Madison
MARY E. MAXON, Lawrence Berkeley National Laboratory
ROBERT NEWMAN, Independent Consultant
STEPHEN J. O'BRIEN, Nova Southeastern University
CLAIRE POMEROY, Albert and Mary Lasker Foundation
MARY E. POWER, University of California, Berkeley
SUSAN RUNDELL SINGER, University of California, Berkeley
LANA SKIRBOLL, Sanofi
DAVID R. WALT, Harvard Medical School

Staff

FRANCES SHARPLES, Director
LIDA ANESTIDOU, Senior Program Officer
KATHERINE BOWMAN, Senior Program Officer
ANDREA HODGSON, Program Officer
JO HUSBANDS, Senior Scholar
KEEGAN SAWYER, Senior Program Officer
AUDREY THEVENON, Program Officer

Acknowledgments

This Proceedings of a Workshop was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published proceedings as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this proceedings:

Kavita Berger, Gryphon Scientific
Gerald L. Epstein, National Defense University
Filippa Lentzos, Kings College London
Sue Meek, The Australian National University

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the content of the proceedings nor did they see the final draft before its release. The review of this proceedings was overseen by **Gary Marchant**, Arizona State University. He was responsible for making certain that an independent examination of this proceedings was carried out in accordance with standards of the National Academies and that all review comments were

carefully considered. Responsibility for the final content rests entirely with the rapporteurs and the National Academies.

The workshop committee and rapporteurs thank the members of cooperative international organizations and of the local organizing committee for their engagement, many valuable comments, and assistance throughout the workshop process: **Jelena Đukić**, Croatian Academy of Sciences and Arts; **Robin Fears**, European Academies Science Advisory Council; **Nevenka Jakopović**, Croatian Society for Biosafety and Biosecurity; **Peter McGrath**, InterAcademy Partnership; **Iva Posavec**, O-Tours PCO d.o.o; and **Ljiljana Žmak**, Croatian Institute of Public Health and School of Medicine at the University of Zagreb.

We also thank those who participated in a special session held in Washington, DC, in May 2018 in advance of the workshop. Due to the global nature of the workshop in Croatia, of necessity only a small number of U.S. participants were able to be included. The special session provided a forum to obtain ideas and views from additional U.S. experts in academic, government, and nonprofit organizations who have been active in addressing dual use concerns. This information helped to inform background materials shared with the international workshop.

Contents

1	INTRODUCTION	1
	Workshop Goals, 1	
	Organization of the Proceedings, 4	
2	GOVERNANCE IN THEORY AND PRACTICE	7
	Governance as a Layered System Across the Research Enterprise, 7	
	Life Sciences Governance in Action, 14	
	Fostering Change, 27	
3	THE CURRENT GOVERNANCE LANDSCAPE	37
	Introduction, 37	
	Breakout Structure and Process, 38	
	The Current Landscape, 41	
	Governance Across the Research Life Cycle, 42	
	Promoting and Sustaining Governance, 58	
	Engagement: Awareness Raising and Outreach, 65	
	Education Efforts and Development of Materials, 66	
	Coordination and Consensus Building, 71	
	Summing Up, 78	
4	WORKSHOP DISCUSSIONS	79
	Introduction, 79	
	Strengthening the Current Governance Landscape, 79	

Governance Activities Across the Research Life Cycle, 85
Engagement, 90
Education, 93
Looking Ahead: Building Success and Sustainability in
Dual Use Governance, 95
Closing Remarks, 96

REFERENCES **99**

APPENDIXES

A Agenda 107
B Participants 113
C Committee Member Biographies 119
D Collaborating Organizations 127
E Examples of Activities Across the Governance Landscape 131
F Examples of Regional and International Forums,
Organizations, or Bodies 145

Figure and Tables

FIGURE

- 2-1 The research life cycle, 10

TABLES

- 3-1 Selected Examples of Governance Activities Across the Research Life Cycle, 43
- 3-2 Selected Examples of Activities That Promote and Sustain Governance, 59
- 3-3 Selected Examples of International Forums, 72
- 4-1 Elements That Could Contribute to an Oversight System for Dual Use Life Sciences Research, 82
- 4-2 Contributions of the Behavioral and Social Sciences to Governance, 85
- 4-3 Examples of Specific Actions Arising from Workshop Discussions, 97

Introduction

WORKSHOP GOALS

Between June 10 and 13, 2018, more than 70 participants from 30 different countries and 5 international organizations took part in an international workshop, *The Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight*, in Zagreb, Croatia. Hosted by the Croatian Academy of Sciences and Arts, the workshop was a collaboration among the InterAcademy Partnership, the Croatian Academy, the Croatian Society for Biosafety and Biosecurity, and the U.S. National Academies of Sciences, Engineering, and Medicine (the National Academies).¹ The workshop was organized by an international committee under the auspices of the National Academies. The opening remarks from the host organizations provided the context for the workshop.

Continuing rapid developments in the life sciences offer the promise of providing tools to meet global challenges in health, agriculture, the environment, and economic development; some of the benefits are already being realized. However, such advances also bring with them new social, ethical, legal, and security challenges. Governance questions form an increasingly important part of the discussions about these advances—whether the particular issue under debate is the development of ethical

¹ Information about the collaborating organizations may be found in Appendix D. The workshop agenda may be found in Appendix A, the list of participants in Appendix B, and the biographies of the members of the planning committee in Appendix C.

principles for human genome editing, how to establish regulatory systems for the safe conduct of field trials of gene drive-modified organisms, or many others. The international community, including the workshop participants and their organizations, is similarly engaged in discussions about the implications of new scientific developments and the implementation of strategies to achieve effective oversight. This workshop reflects continuing concerns that the knowledge, tools, and techniques resulting from life sciences research could also enable the development of bioweapons or facilitate bioterrorism. Certain life sciences research is thus “dual use;” that is, although intended to serve beneficial purposes, it could also be misused to cause harm.² The workshop did not address the broader set of social, ethical, and legal implications associated with *international* governance of life sciences research, although experiences in other domains may be relevant to approaches to governance in response to biosecurity concerns.

The workshop focused on the critical challenge of how to create and support effective systems of governance for life sciences research that may raise dual use concerns. A number of countries in different parts of the world have developed oversight policies that apply to specific experiments, often those that seek to make particular types of changes to certain pathogens. Research funding bodies, both public and private, are considering and incorporating dual use assessments into their funding reviews. Journal publishers have released statements on biosecurity and scientific publishing and created policies to include biosecurity issues in manuscript reviews and respond if concerns emerge. Members of the scientific and policy communities have been conducting outreach to raise awareness of biosecurity concerns and scientific responsibilities. The Biological and Toxin Weapons Convention (BWC), a key part of the foundation of the wider regime, and other venues provide opportunities where the security implications of life sciences advances are considered. This landscape provides a set of diverse efforts and activities on which to draw.

An important goal for this workshop was to contribute to ongoing

² Traditionally, “dual use” has been used in disarmament and arms control to denote “goods, software and technology that can be used for both civilian and military applications” (European Commission, “Dual-use Trade Controls”). Available at <http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls> (accessed October 2, 2018). The different concept was introduced by a 2004 National Research Council report, *Biotechnology Research in the Age of Terrorism*, which called the potential for such unintended consequences “the dual use dilemma” (NRC, 2004: 1; known as the Fink report for the committee’s chair, Gerald Fink). This latter use is the focus of this proceedings, recognizing that there can be confusion because, as discussed in the text, laws and regulations designed to address traditional dual use issues are now frequently used to address oversight of research with dual use potential.

global dialogue and the building of common understandings of the essential elements of governance for life sciences research that raises biosecurity and dual use concerns. Fostering such global discussion and coordination will ultimately be necessary to achieving a strong and effective governance system.

Sue Meek, Chair of the Planning Committee, built on the opening remarks to outline the specific goals of the workshop. The workshop had been designed to bring together people actively involved in developing or implementing governance of dual use research to

- Share experiences and better understand the recent and current landscape of dual use governance activities;
- Discuss what has worked and not worked, analyze lessons learned, and explore gaps and opportunities; and
- Identify concrete actions and next steps to fill gaps and take advantage of opportunities.

She also provided further background, noting that while “dual use” research comprises “research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be misused to cause deliberate harm,” many efforts toward dual use governance are focused on pathogen research (U.S. Government, 2012: 5). For example, the U.S. governance system focuses on Dual Use Research of Concern (DURC), a subset of dual use that covers only certain types of experiments with specified biological agents and toxins.

Meek emphasized that, for the purpose of the workshop, discussion should encompass the wider definition and not be limited to the narrower scope of U.S. DURC policy. She also encouraged participants to think broadly about how to create strong, flexible, and anticipatory systems of governance for dual use life sciences research. Additionally, she suggested that there were new developments, such as the genome editing technology CRISPR,³ that represent a step-level change in the capacity and availability of technology that may require existing governance systems to be adapted and amended.

To set the stage for the next portion of the workshop, Meek provided an introduction to the topic of governance, indicating that, while some see this as fundamentally about legislation and regulation, there are other

³ Clustered regularly interspaced short palindromic repeats (CRISPR) “refers to short, repeated segments of DNA originally discovered in bacteria. These segments provided the foundation for the development of a system that combines short RNA sequences paired with Cas9 (CRISPR associated protein 9, an RNA-directed nuclease), or with similar nucleases, and can readily be programmed to edit specific segments of DNA” (NASEM, 2017a: 2).

ways of achieving this objective. As the plenary speakers would discuss, dual use governance cuts across multiple organizations and involves multiple actors, each of whom may make valuable contributions. Governance can thus be developed through additional means, such as networks and codes of conduct.

She suggested that effective implementation required going beyond “box-checking” exercises, where there may be inadequate consideration of the context or meaning of the boxes, adding that the effectiveness of governance frameworks depends on a number of different factors. These include

- principles for dual use governance that are well written, encompassing, and understood by those affected;
- established norms of responsible conduct of research, something that requires engaging with scientists and encouraging them to consider such issues proactively, ideally before starting research projects;
- cultural change, and she suggested that there is no point in introducing codes of conduct if the organizational culture does not view compliance with such codes as important; and
- outreach, education, and training efforts to make sure that people are aware of codes and other governance measures.

Meek commented that this last element required an understanding of suitable methods and approaches to encourage engagement. In conclusion, she argued that regulation was not necessarily always the answer and that no one system was going to fit all circumstances, as different regulatory systems and cultures demand different solutions. She suggested that a network of networks could be a valuable concept to increase awareness and to share knowledge.

ORGANIZATION OF THE PROCEEDINGS

The planning committee designed the workshop to encourage participation and frank discussion, with a mix of plenary and breakout discussion sessions and participants from diverse countries reflecting a range of expertise. The plenary sessions devoted to particular topics and issues are summarized in Chapter 2, while examples of the landscape of current governance activities are presented in Chapter 3. The results of the workshop discussions are presented thematically in Chapter 4. The workshop proceedings, prepared by rapporteurs and produced by the U.S. National Academies, summarizes the remarks of speakers and views expressed by individual workshop participants. In her opening remarks

Meek encouraged the participants to engage actively and noted that their contributions would form the basis of the eventual content of the workshop proceedings.

This proceedings was prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. The planning committee's role was limited to organizing and convening the workshop. This workshop and proceedings address a major and complex set of issues in governance of life sciences research. The workshop could not give full consideration to all issues, arguments, and references relevant to this topic; the views contained in the proceedings are those of individual workshop participants and do not necessarily represent the views of all workshop participants, the planning committee, or the U.S. National Academies.

Governance in Theory and Practice

This chapter summarizes the substantive presentations and accompanying discussions during plenary sessions that provided background and context for the participants. Copies of the presentations are also available on the project website.¹

GOVERNANCE AS A LAYERED SYSTEM ACROSS THE RESEARCH ENTERPRISE

Following the introduction to the goals of the workshop, Alta Charo of the University of Wisconsin–Madison further elaborated on the concept of governance. Beginning at the international level, Charo emphasized that no single international institution has the mandate and capacity to provide oversight of dual use biotechnologies. She noted that a number of institutions provide or could provide a forum for discussions of dual use issues to develop common understandings and approaches to action. The cornerstone of the biological disarmament and nonproliferation regime is the Biological and Toxin Weapons Convention (BWC), which builds on the 1925 Geneva Protocol banning the use of chemical and biological agents in war. The BWC addresses aspects of research indirectly through a prohibition on developing, producing, stockpiling, or otherwise acquir-

¹ The project website is available at National Academies of Sciences, Engineering, and Medicine, Governance of Dual Use Research in the Life Sciences: An International Workshop. Available at <http://nas-sites.org/dels/events/dual-use-governance> (accessed September 4, 2018).

ing or retaining “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” (Biological Weapons Convention, 1972). This indirect link to research provides little clarity on what types of research, including defensive research, are or are not acceptable. The treaty lacks formal mechanisms to verify compliance with its provisions or respond to violations, but serves as an important forum for discussions of dual use issues and a focus for international efforts to develop common understandings about research practices and oversight.

Charo next outlined a number of different approaches to analyzing the governance of biotechnology. One approach is to look at the actors involved. The work of Migone and Howlett (2009) on genomic policy making, for example, identified four key categories of actors. The first, governments, played a role as funders and regulators of research, and the second, universities, were producers of basic and applied research. The third category was private-sector bodies that functioned as users and producers of innovation (as well as financiers and thereby sources of governance themselves). The final category was the public, who may be both consumers and critics.

A second approach is to focus on different regulatory issues, and Charo illustrated this by drawing on a framework developed for agricultural applications that included intellectual property rights, public information, retail and trade, food and health safety, consumer choice, and public research investment (Haga and Willard, 2006: 967). Charo explained that different regulatory issues faced differing research, legal, economic, educational, and acceptance challenges, and that the framework could be explored to look at how policy options stifle or promote research. She used issues around consumer choice to illustrate that the more technology is accepted, the more investment will flow into it and the larger the scale of research and development will be. This in turn changes how and where the technology is used in the food chain, affecting its capacity for diversion into destructive uses and the opportunities at which governance can take place.

Building on this point, Charo discussed the model developed by Robert Paarlberg in his studies of approaches to policy for genetically modified foods to illustrate how options operate along a spectrum, ranging from “promotional” to “preventive” (Paarlberg, 2000: 6). Using the case of intellectual property rights, she argued that patents could be seen as promotional because they encourage investment, whereas if intellectual property rights are eliminated, business interest is eliminated as well. For biosafety, policies could take either a promotional or a preventive approach. With the promotional approach, the technology is assumed to

be safe, and no specialized review is required without a specific signal of hazard. By contrast, with a preventative approach, risk is assumed, and everything is viewed as dangerous until proven safe. In between lies a case-by-case review in which each use is examined, with neither safety nor hazard assumed. The speed of introduction into the market (or into research use) depends largely on which approach is taken.

Charo suggested that, while many people associate governance with regulations and laws, it would be more useful to think of governance as an “ecosystem” in which there are many different types of actors and multiple instruments that can be applied. The actors involved include funders of life sciences research; scientists from both academia and industry; institutions, such as universities and medical centers; journal publishers and others involved in disseminating research results; national governments; and regional and international bodies. The instruments include obvious measures such as treaties, laws, regulations, and policies, and restrictions on funding from public sources. In addition, other measures such as self-governance activities undertaken by the scientific community on a voluntary basis, are also important to responsible conduct of research, as had been the case in her experience with the governance of embryonic stem cell research.² And she commented that there are also a number of other instruments that do not receive much attention in discussions of dual use issues, including intellectual property rights, restrictions by private funders, material transfer restrictions, oversight committees, and advisory bodies and stakeholder/advocacy groups.

She provided a number of specific examples of the different parts of the ecosystem, which are described in greater detail in Chapter 3. Charo began with formal legal measures, citing the obligations imposed at the international level by the BWC to put in place implementing legislation. As a second example she cited the work undertaken by the government of Pakistan, which included both a number of different legislative efforts related to dual use research as well as a number of administrative activities.

As an example of nonlegislative or regulatory measures, Charo cited the United Kingdom, where there have been a number of self-governance initiatives by the scientific community, including activities by the academic community, learned societies, and professional bodies to provide

² The International Society for Stem Cell Research has developed widely accepted guidelines for the conduct of research using stem cells (see International Society for Stem Cell Research, Guidelines for Stem Cell Research and Clinical Translation). Available at <http://www.isscr.org/membership/policy/2016-guidelines/guidelines-for-stem-cell-research-and-clinical-translation> (accessed September 18, 2018).

Initial Conception and Planning	Funding	Conduct of Research	Dissemination of Results	Translation and Product Development
---------------------------------	---------	---------------------	--------------------------	-------------------------------------

FIGURE 2-1 The research life cycle.

education and training and to promote responsible research.³ She mentioned that, in Portugal, dual use research and Dual Use Research of Concern (DURC) are overseen by “biosecurity committees within institutions and informal bottom-up awareness-raising activities” (Millett, 2017). She also raised several examples of opportunities from education, including the case studies produced by the Federation of American Scientists and various resources from the Bradford Disarmament Research Centre (see Appendix E).

Charo stressed the importance of governance activities at every stage of the research “life cycle”: conception and initial planning; funding; conduct of research; dissemination of results; and translation and product development (see Figure 2-1).

At the conceptual or initial planning stage there are basic choices in approaching governance. Such choices in the private sector could include whether “dangerous” information would be subject to trade secrets and therefore hidden, with fewer people having open access, or taken forward through patents, thereby making potentially dangerous information open. In the U.S. context, the initial planning stage for publicly funded research would involve oversight bodies for biotechnology research, including reviews by an Institutional Biosafety Committee (IBC), and since 2015, the additional policy changes, oversight, and consultations required in cases of research involving DURC agents and experiments (U.S. Government, 2014a).⁴ She elaborated on the 15 DURC agents and the 7 categories of

³ At the time of the workshop, the United Kingdom was finalizing its first Biological Security Strategy, released in July 2018 (UK Home Office, 2018).

⁴ U.S. Dual Use Research of Concern (DURC) policy applies to specific types of experiments with specified biological agents and toxins that “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” (U.S. Government, 2012: 1–2). The 15 agents and toxins are (a) avian influenza virus (highly pathogenic), (b) *Bacillus anthracis*, (c) botulinum neurotoxin, (d) *Burkholderia mallei*, (e) *Burkholderia pseudomallei*, (f) Ebola virus, (g) foot-and-mouth disease virus, (h) *Francisella tularensis*, (i) Marburg virus, (j) reconstructed 1918 Influenza virus, (k) rinderpest virus, (l) toxin-producing strains of *Clostridium botulinum*, (m) *Variola major* virus, (n) *Variola minor* virus, and (o) *Yersinia pestis*. The policy applies to an experiment if it “a) Enhances the harmful consequences of the agent or toxin; b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification; c)

experiments that are the focus of current DURC policy to illustrate how this limited list was intended to identify core concerns. When it comes to institutional review under the DURC policy, the initial responsibility lies with the principal investigators (PIs) to identify potential DURC, which is then subject to an institutional review process. The objective is to identify the anticipated benefits, in conjunction with the risks, and if necessary develop a “risk mitigation plan.”

Funding decisions are a second important phase, and one that is subject to different national approaches. In the case of the United States, in 2017 the White House Office of Science and Technology Policy recommended, in addition to the existing DURC policy, prefunding review mechanisms for federal agencies that “conduct or support the creation, transfer, or use of enhanced pathogens of pandemic potential” (U.S. Government, 2017: 1). In the United Kingdom, the three largest funders of life sciences research, two government agencies and one private foundation, jointly require applicants to consider the risks of misuse associated with their proposal, and reviewers are given guidance for assessing cases (BBSRC et al., 2015). In the European Union, she noted that “research grant applications are subject to an ethical review panel and a security scrutiny committee can be convened if a research project has ethical or security implications” (Lentzos, 2015: 11).

A third phase identified by Charo was the conduct of research. Risk mitigation measures identified as relevant to this area include modifying the design or conduct of the research, enhancing security at laboratory facilities, and restrictions on personnel. Another measure that had received less attention in this phase was the incorporation of biological control mechanisms into research. For example, this approach is being employed in the Defense Advanced Research Projects Agency (DARPA) Safe Genes program.⁵ She suggested that such mechanisms can provide additional biological safeguards to complement the physical safeguards of the laboratory. Her final example of governance measures in the conduct of research was examining the efficacy of existing medical countermeasures and, where required, conducting experiments to determine their efficacy against agents and toxins resulting from dual use research.

Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies; d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; e) Alters the host range or tropism of the agent or toxin; f) Enhances the susceptibility of a host population to the agent or toxin; or g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above” (U.S. Government, 2012: 7–8).

⁵ Information on the program is available at Defense Advanced Research Projects Agency, “Safe Genes.” Available at <https://www.darpa.mil/program/safe-genes> (accessed September 4, 2018).

The fourth phase of the research life cycle concerned the dissemination of results. Charo noted that the principle of free movement of ideas was crucial to journalism and science; yet at the same time there was some awareness that there could be occasions where the publication of information can be more harmful than helpful. She provided examples of past initiatives in this area, highlighting how these extend beyond formal classification processes. The first example was the 2003 statement by leading journals endorsing review of manuscripts for dual use material (Journal Editors and Authors Group, 2003), and the second was the white paper prepared by the Council of Science Editors, which made a similar call (Council of Science Editors, 2018).

Finally, in terms of the fifth phase, translation, Charo noted that there are export controls and technical innovations to control or limit spread (e.g., the DARPA Safe Genes program). Additionally, owners of intellectual property can act as a significant source of governance through the use of conditions on patent licenses and material transfer agreements to control uses and third-party dissemination. She provided an example of how this had been employed in the area of stem cells, wherein intellectual property owners were in a position to put conditions into every license stipulating that the intellectual property could (or could not) be used for cloning. She suggested that this was an existing avenue that needs to be given more attention.

Charo's talk was followed by insights provided by Michele Garfinkel of the European Molecular Biology Organization (EMBO) from the perspective of the individual researcher, drawing on her experience and understanding of how researchers think and operate on a daily basis. Garfinkel argued that, in her experience, researchers generally want to do the right thing, are embedded in society, and primarily just want to do science. However, she continued, researchers do not have time to think in depth about concepts related to dual use governance, and she cautioned that if outreach and engagement are not done properly, dual use governance could become perceived as simply another element of the "bucket of things" that get in the way of research. Finding ways to avoid this reflexive rejection by researchers is essential to fostering effective governance.

Garfinkel also discussed the importance of intellectual property and funders, with the latter particularly important in the funding review process and in encouraging investigators to provide reassurance by supporting training in responsible research. In the current European context, she suggested that grant recipients often received no training in responsible research generally, let alone dual use-specific training. Accordingly, EMBO had provided training courses on the topic to fill the gaps, and she encouraged more efforts by funders to provide training for grantees.

Garfinkel also highlighted the importance of journals, given their

power to stop publications and also to assist researchers in understanding when their research might be dual use through the use of prepublication checklists, and through posteditorial, prepublication discussions with authors and editors. She explained that EMBO journals are run by professional editors who consider issues such as dual use as part of their publication process. In addition, EMBO makes use of an appointed board that includes people who are knowledgeable about dual use concerns. Many other journals, however, depend on volunteer academic editors who do not necessarily have a great deal of time or much knowledge of dual use issues and are therefore less well placed to support governance at this stage. She also noted that publication is the last chance to catch problems and, if an issue related to dual use is submitted to publication, then there must have been failures of oversight during the process. Garfinkel concluded by commenting that changes can take time to be fully implemented, even when ideas for change come from within the community.

Discussion

In the ensuing discussion, participants raised a number of points. One participant had concerns about private-sector research and the extent of controls in the entrepreneurial sector, arguing that there are no requirements to publish in the private sector and, in some cases, research only becomes visible through intellectual property. The participant suggested that government funding for academic research ensured that there is a degree of control, but not in the case in the private sector. Other participants countered this suggestion, arguing that many companies in the private sector had undertaken voluntary measures in support of dual use governance. It was suggested that this demonstrated some awareness of the challenges of dual use governance, as well as private-sector support for governance-related activities.

The role of publishers was also discussed further, with one participant echoing Garfinkel's comments about some of the challenges faced by academic editors and the lack of knowledge of dual use-related issues among some editors. As other participants noted, this increased the chances that peer-review processes would fail to catch dual use issues. Others suggested that these challenges were being confounded by the emerging practice of prepublication, in which researchers post papers online prior to the completion of the peer-review process. The trend toward prepublication dissemination practices could considerably undermine the role of publishers as an intervention point for dual use governance.

The notion of an ecosystem of governance was also discussed, with one participant concerned that substantial changes in the regulatory ecosystem along with the rapid progress of science had rendered it dysfunc-

tional and there was a need for governments to catch up. Participants presented some initial thoughts about how this could be achieved, with one identifying a need for coordination through a clearinghouse-type mechanism so that people seeking advice and guidance on what to do with a manuscript that raises dual use concerns would know where to go. Another suggested there could be a scope for a system with different levels of scrutiny depending on the reputation of the organization. According to this logic, which built on the notion of “consistently trusted exporters,” organizations with higher standards would be subject to lower levels of oversight, whereas new actors or those with lower standards would be subject to more scrutiny.

LIFE SCIENCES GOVERNANCE IN ACTION

The second plenary, led by Iqbal Parker of the University of Cape Town, was divided into two sections. The first was an introduction to recent examples of life sciences research with dual use implications; the second was a panel with presentations providing examples of life sciences governance activities, outcomes, and lessons. He opened the plenary by describing some of his own experiences with biosafety and security governance activities undertaken in the context of South and sub-Saharan Africa as an example of the roles that academies of science can play. He described an assessment of existing legislation and regulations undertaken by the South African Academy of Sciences at the request of the South African government to identify strengths and weaknesses of such measures; provide a critical overview of measures in laboratories in southern Africa; conduct an assessment of dual use concerns; and evaluate existing measures and capacity to prevent natural, accidental, and deliberate events. The report, issued in 2015, raised concerns about both the legislation and the implementation of measures related to biosecurity and biosafety (Academy of Sciences of South Africa, 2015). A subsequent regional workshop for southern Africa on March 19 and 20, 2018, in Johannesburg, South Africa, provided an opportunity to discuss the topic further (Academy of Sciences of South Africa, 2018). Parker concluded by emphasizing the importance of avoiding cumbersome regulatory structures in these areas.

Examples of Research with Dual Use Implications

The first speaker, Piers Millett of the iGEM Foundation, provided an introduction to examples of recent life sciences research with dual use implications. Millett began with a short overview of the International Genetically Engineered Machine (iGEM) competition, which engages

undergraduate and high school teams who spend a summer engineering biological systems using standardized parts to address real-world challenges.⁶ The speaker noted that last year some 6,000 participants from 340 teams around the world participated in iGEM. Millett then described how the iGEM safety committee has developed robust safety and security practices that are used to guide participants.

Millett stressed that even when research has dual use implications, invariably it has been undertaken for legitimate reasons. He echoed the Fink report's conclusion that just because research had dual use implications did not mean it should not be done (NRC, 2004: 5–6), and he stated that there are a variety of different risk mitigation techniques that can be employed to minimize risks of dual use research. He then provided examples of actual experiments that have provoked controversies about potential dual use implications.

The first example he gave was the chemical synthesis of polio (Cello et al., 2002). The research demonstrated that the functional equivalent of a virus can be created through processes of chemical synthesis. If one can chemically synthesize viruses, it provides a new way for those with hostile intent to acquire dangerous pathogens and evade export controls. The second example was research to reconstruct the virus that caused the 1918 influenza pandemic (Tumpey et al., 2005). Millett noted that, prior to this research, the 1918 flu virus did not exist on the planet in a functional state and, as such, no one had access to it. However, this research potentially allowed nefarious actors to obtain things that would not otherwise exist.

Millett then described how it has now become possible to produce large pieces of DNA. This had raised concerns around whether it might be practically possible to synthetically produce large, complex viruses that do not have a natural reservoir. A particular concern identified by the security community was the creation of highly complex orthopox viruses. He pointed to research on the synthetic construction of infectious horsepox virus, which had been synthesized and rebooted by researchers,⁷ noting that this was important because of the similar relationship between horsepox and vaccinia virus vaccines (Noyce et al., 2018). The research thus raised biosecurity concerns as it demonstrated the possibility of making smallpox, which is otherwise only found in two secure laboratories in Russia and the United States. Additionally, the research raised concerns

⁶ More information about iGEM may be found at International Genetically Engineered Machine Competition. Available at http://igem.org/Main_Page (accessed September 4, 2018), with safety and security issues addressed at "Safety & Security at iGEM." Available at <http://igem.org/Safety> (accessed September 4, 2018).

⁷ Additional steps are required to go from a synthesized viral genome to a viable organism. "The process of inducing raw genetic material to perform biological functions is known as 'booting,' a term borrowed from computer technology" (NASEM 2018: 194).

that it had changed the nature of the research field by both expanding knowledge of smallpox and lowering technical barriers to the creation of such viruses (DiEuliis et al., 2017).

Millett next provided examples of dual use research projects that could fall under each of the seven experiments of concern originally identified in the work of the Fink committee (NRC, 2004: 5–6) and now the focus of U.S. DURC policy. First was research that made vaccines ineffective. Research in this area was exemplified by the mousepox interleukin-4 (IL-4) experiment (Jackson et al., 2001), along with subsequent work on the expression of rabbit IL-4 (Kerr et al., 2004). Second were experiments that would confer resistance to antibiotics or antivirals. Millett indicated that this was evident in research on the regulators of multidrug resistance in *Yersinia pestis* (Galimand et al., 1997). Third was research on enhancing virulence, and he noted that research has been undertaken on elucidating variations in the nucleotide sequence of Ebola virus associated with increasing pathogenicity (Dowall et al., 2014). Fourth and fifth were experiments that involved increasing transmissibility of pathogens and expanding the host range, respectively. These aspects of DURC were clearly evident in the gain-of-function research conducted by Fouchier (Russell et al., 2012) and Kawaoka (Imai et al., 2012), which had been discussed at length (see, for example, NASEM, 2016; NRC, 2013, 2015). Sixth was research on the evasion of diagnostics. Millett identified a paper that studied the manipulation of surface proteins, as this essentially involved making diagnosis more difficult (Anisimov, 1999). Finally, with regard to improved weaponization, research had been undertaken that explored the role of large porous particles for pulmonary drug delivery (Edwards et al., 1997).

Millett proceeded by highlighting four conclusions he believed needed to be considered in the governance of dual use research in the life sciences. The first was the importance of “information hazard management.” He commented that governance measures have traditionally focused on physical controls and restricting access to physical materials. However, the examples discussed above illustrated the importance of looking not only at materials, but also at information and differentiating between the regulation of products on the one hand, and knowledge and information on the other. The latter, Millett argued, lay at the heart of the dual use issues and required policies of information hazard management and management of communications to minimize risks.

His second conclusion was the importance of addressing dual use issues prior to publication stage. He noted that in most of the research examples highlighted above, the debate over dual use took place at the publication stage. This was too late; governance efforts should not wait to address dual use at the point of publication. The third conclusion was the

need for greater awareness and willingness among scientists to address potential risks of research. This required making people aware of the potential for their work to be used for malicious purposes. He considered this to be a big, but not impossible, task. Fourth, and finally, he emphasized that this was not just about pathogens. The importance of thinking beyond pathogens was illustrated by his experience in iGEM, when one team came close to developing a gene drive. This was only picked up toward the end of the competition because none of the parts used were on iGEM control lists and it had not triggered any attention. Millett noted that iGEM had since created a specific gene drive policy under which teams are not allowed to create gene drives without permission from the safety committee.

Examples of Life Sciences Governance Activities, Outcomes, and Lessons

Following the introduction by Millett, the workshop moved to a panel format with a focus on examples of life sciences governance involving different activities and actors.

Governance of Dual Use Research in the Life Sciences in Australia

The first panel speaker was Julia Bowett of Australia's Department of Defence Export Control Branch who drew from her expertise as both a technical adviser on export controls in the life sciences area and a co-chair in the Australia Group. Bowett introduced the Australia Group as an informal arrangement among 42 countries plus the European Union as an institution that meets annually to discuss trade restrictions on certain sensitive technologies of concern in order to counter the proliferation of chemical and biological weapons.⁸

She then outlined Australia's approach to export controls, and the lead role of the Department of Defence in controlling traditional dual use items, that is, those with military utility as well as uses in legitimate research, commercial, or industrial uses. Controlled goods or technologies are listed in a document called the Defence and Strategic Goods List (or the DSG), which is developed in conjunction with members of various international nonproliferation and export control regimes.⁹ The DSG

⁸ More information may be found at The Australia Group. Available at <https://australiagroup.net/en/index.html> (accessed September 4, 2018).

⁹ The list and supporting information are available at Australian Government Department of Defence, "Defence and Strategic Goods List." Available at <http://www.defence.gov.au/ExportControls/DSGL.asp> (accessed September 4, 2018).

is divided into two parts: the first contains goods and technologies that are designed for military purposes, such as munitions, explosives, and training equipment; the second contains dual use goods and technologies that may be used in a military program or could contribute to the development or production of chemical, biological, or nuclear weapons. This includes items such as chemicals, pathogens, toxins, electronics, computers, sensors and lasers, and navigation and avionics equipment. Bowett noted that some of these items required an export license if they met specific technical criteria.

With regard to the life sciences, the list of controlled items includes a number of human, animal, and plant pathogens and toxins (including various types of bacteria, viruses, and fungi), along with certain genetic materials and genetically modified organisms (GMOs). Listed agents are controlled under circumstances that include, for example, isolation of live pathogen cultures, extraction of a toxin, or inoculation of living material with a listed agent. Dual use equipment and chemicals are also regulated, including biological agent production equipment such as high-containment-level facilities, centrifugal separators, and fermenters; chemical production equipment such as reaction vessels, reactors, agitators, condensers, and pumps; and 65 chemical weapon precursors.

Regulations address two different types of exports. The first is tangible exports of physical items sent outside Australia by sea freight or air cargo or carried by a person; the second is the supply of intangible technology, which refers to non-physical assets such as information. The second category has the greatest connection to dual use research. The regulations for both types of exports apply to industry, universities, and research sectors.

Recognizing the complexities of the issues, the Australian government set out to create an open-source Life Sciences Guide (Australian Government Department of Defence, 2016). To ensure regular feedback from the life sciences sector in Australia, a working group made up of representatives from universities, research institutes, public health networks, and other government agencies was created. Consultations with the working group extended for approximately 2 years over the various iterations of the Guide. Bowett commented that the Guide included all of the controls that might apply to life scientists and the exemptions the Australian government makes available to them. The working group also addressed sector-specific concerns using scenarios and she provided several illustrative examples.

The single biggest challenge for the regime, Bowett argued, is dealing with the intangible transfer of technology and the electronic supply of information over email or via cloud computing. This is a challenge for governments the world over, not just Australia. As an example of intan-

gible technology supply that would require a permit, she presented the case in which someone in Australia collaborates with an entity in Japan to create a new method of developing an export-controlled pathogen (e.g., Lassa fever virus), and the Australian entity emails the research findings to the Japanese entity. A second challenge is understanding university culture, and she posited there was a need to find a very fine balance between the needs of the research community in Australia and the requirements of the counterproliferation obligations that the Australian government has undertaken. A related challenge is addressing misunderstandings, such as explaining specifically where the thresholds for export controls lie, when researchers should talk to the government, and what amounts to a “supply” of technology.

Bowett concluded by stressing the importance of providing information to the regulated community and elaborated on the extensive outreach that Australian export control authorities had conducted to universities, public health networks, and companies, including through a “capital cities roadshow” each year. She commented that the roadshow sessions in particular invariably reached capacity. Every university in Australia now has an export control manager who serves as a point of contact for the regulators, and with whom they maintain good working relationships. She stated that if a university or company requests assistance for a major project, the authorities invariably visited them and walked them through the export controls that apply, explaining what they have to do. Additionally, the team at the Australian Defence Export Controls Branch provided a free export control helpline and frequently presented at conferences and expos.

Governance of Dual Use Research in the Life Sciences

Joseph Kanabrocki of The University of Chicago, the second panelist, introduced himself as a faculty member who also oversaw the research safety office. To begin, he provided an overview of The University of Chicago, indicating that it supports nearly \$500 million in externally sponsored research annually and involves approximately 400 principal investigator (PI)-led research groups, with approximately 300 PI laboratories in the Biological Sciences Division.

He indicated that the university had two IBCs; one on the main campus at Hyde Park and a second in its Select Agent High Containment Facility. When the U.S. government created its policies for oversight of DURC for institutions receiving federal funds in 2014, it also included a requirement to create an Institutional Review Entity (IRE) in addition to the IBC (U.S. Government, 2014a). In the case of the University, its IRE (also called the DURC Task Force) includes a diverse range of mem-

bers: those involved in DURC, as well as participants from the Office of Research, which includes those dealing with export controls, the Office of General Counsel, and faculty members who are also members of one or both of the University's IBCs. He commented that DURC was the driving force for this task force but the program was not limited to the 15 agents and 7 experimental approaches detailed in the U.S. DURC policy.

The University of Chicago's DURC governance structure begins with the PIs, who are in constant communication with the IBC. The Office of Research Administration works with PIs and funding agencies, thereby closing the circle. In their traditional role, the IBCs require the registration of recombinant DNA work and/or any project that involves human, animal, or plant pathogens. When protocols for associated work are registered, the IBCs attach certain training requirements and Kanabrocki indicated that no protocol can be approved without the training system attached to it. Additionally, PIs are required to answer questions about whether the proposed research plan would involve experiments in any of the seven areas of concern identified by the Fink committee (NRC, 2004: 5–6). He commented that sometimes PIs answer “no” to all the questions because they do not understand what they are working with; others check “yes” to ones that are not relevant. Yet although there may be confusion over the questions, he argued that the process of using this questionnaire was a form of education in and of itself.

Kanabrocki said there were two types of review for DURC: the first was at the beginning when the proposal is written, when they undertook an initial review, and a second at the end, when the manuscripts are written. Based on the outcome of the first review, the DURC Task Force provides binding recommendations and supervision related to the conduct of the DURC. The University has developed a Framework for Review of Risk Mitigation Plans with four steps, following the guidance provided by the U.S. government. The first involves “[a review of] the research to verify that it still directly involves nonattenuated forms of one or more of the listed agents.” The second step involves “[assessing] whether the research still produces, aims to produce, or can be reasonably anticipated to produce one or more of the listed experimental effects.” The third step is to “determine whether the research still meets the definition of DURC,” and the fourth is to “review and, as necessary, revise the risk mitigation plan” (U.S. Government, 2014b: 44).

He also described a number of possible risk mitigation measures. These included consideration of—and changes to—the “timing, mode, or venue of communication for the DURC in question,” as well as “[establishing] a mechanism for prepublication or precommunication review by the institution and/or the appropriate USG funding agency” (U.S. Government, 2014b: 38). On the latter point, he commented that mecha-

nisms for prepublication review are often not well received and PIs are eager to publish their work. Other risk mitigation measures employed in communicating DURC could include adding material to the text to “emphasize the biosafety and biosecurity measures that were in place throughout the course of the research” (U.S. Government, 2014b: 38), and placing emphasis on the public health benefits, thereby focusing attention on the benefits rather than the potential harm.

He indicated that there were common elements in all of the University’s DURC risk mitigation plans, including a description of the enhanced biosafety and biosecurity measures in place in all formal communications (e.g., manuscript, abstract, poster, etc.); training investigators about DURC; the provision of a forum for ongoing monitoring of DURC projects; and the creation of a code of ethical conduct for all researchers. In addition, for work involving Select Agents, the code is signed annually by all investigators and discussed during annual interviews. The code includes commitments to standard practices of responsible conduct, but also an obligation to report accidents and injuries as well as suspicious behavior.

Kanabrocki concluded by addressing some programmatic limitations experienced by the university. For example, the program was limited to the life sciences as the university did not have an in-house mechanism to review physical science experiments as systematically as it does life sciences experiments. Moreover, the current regulatory framework is list based, which makes little sense to him as some of the experiments do not fit easily within the categories. He also acknowledged that there is limited screening of molecular engineering and synthetic biology research and the current mechanisms for dual use research screening rely on a risk mitigation platform originally established for the oversight of work with recombinant DNA. Nonetheless, he concluded that it was a start and the current screening paradigm provides a platform for the development and delivery of dual use research education and puts consideration of DURC on investigators’ radar screens.

*Role of Young Academies in Promoting Responsible Conduct of Research:
The Malaysian Experience*

The third panelist was Abhi Veerakumarasivam from Sunway University. Veerakumarasivam began by emphasizing the importance of striking a balance between research activity for progress on the one hand, and regulations intended to protect on the other. He presented presented citation data from different countries between 1996 and 2016 indicating the sizeable number of papers produced by Southeast Asian countries such as Indonesia, Malaysia, Singapore, Thailand, and Vietnam. This

reflects the aspirations of many such countries to become world class in scientific research and, they hoped, improve their economic situation. Yet as research became more extensive, so too did the spotlight on research concerns, and he indicated that they had experiences with both high-profile retractions of publications and apprehensions over nefarious activities. This underscored his argument for the need to balance research and protection, taking into account that much of the research was undertaken to serve humanity.

Veerakumarasivam outlined the history of the responsible conduct of research program in Malaysia beginning with a workshop in 2013 that was organized by the U.S. National Academy of Sciences (NAS), which provided many in the region with an introduction to the concept of responsible conduct of research (RCR).¹⁰ He indicated that the introduction to active learning pedagogy as part of the workshop had an immediate impact, as they had not thought much about this issue before. He further noted the importance of collegiality at this event and outlined how subsequently the NAS allocated funding for four further workshops to introduce RCR and active learning. These workshops helped in building critical capacity, generating momentum, and, perhaps more importantly, developing a greater understanding of the local context.

He discussed the levels of awareness among the participants, indicating that the majority had never attended RCR training and were unaware of whether their universities provided clear guidance for addressing research misconduct. He suggested that biosecurity and dual use research were the least understood in terms of RCR knowledge and the workshops were able to “double” knowledge levels. It was also noted that there were large variations in awareness evident across individuals and, as he pointed out, when asked the question, “When you witness your colleague committing research misconduct, what would you do?” senior experienced researchers (i.e., those with more than 10 years of experience) were more inclined to inaction. This suggested to him that there was utility in the voices of young people.

Next, he discussed some of the challenges to global harmonization and identified a number of issues. The first was the desire for greater national competitiveness; the second was that dual use issues were seen by some as a Western initiative and were met with both skepticism and cynicism. He suggested this perhaps reflected the inability to contextualize on the part of some. The third challenge to global harmonization was gaps in the capacity of relevant actors to conduct, assess, and monitor

¹⁰ For further information, see National Academies of Sciences, Engineering, and Medicine, “Educational Institute on Responsible Science (SE Asia).” Available at <http://nas-sites.org/responsiblescience/iircs/institutes/institute-in-se-asia> (accessed September 20, 2018).

activities. A final challenge was posed by differences in religion, culture, and values that may affect which issues are perceived to be of greatest relevance and concern. He also noted that there were issues with risk perception and response and, even when hazards are known, risks are still taken, with risk perception often proving to be context specific.

Veerakumarasivam also discussed the results of a report from the Global Young Academy about the heterogeneity of the global state of young scientists in the Association of Southeast Asian Nations (ASEAN) (Geffers et al., 2017) and emphasized the importance of creating spaces and training opportunities for young scientists in the region. He noted that his experience in the ASEAN science leadership program suggested that young people are both concerned about and interested in topics related to responsible conduct. He described the launch of the Malaysian code of responsible conduct of research and the establishment of an educational module (Chau et al., 2018). He added that the educational module included a dedicated chapter on addressing dual use issues in the Malaysian context. Veerakumarasivam noted that they had tried to address issues beyond life sciences and dual use, and to engage engineers and physicists, for example. He added that there was an ASEAN young scientists group trying to create a larger group of trainers in this area, and concluded by noting that first, the experience thus far would not have been possible without the help of the NAS, and second, that education is key and young scientists are important.

Neuroenhancement, Responsible Research, and Innovation

The final panel speaker was Agnes Allansdottir of the Toscana Life Sciences Foundation, who spoke about a project that illustrated governance of research with dual use potential beyond pathogens. Neuroenhancement, Responsible Research, and Innovation (NERRI) was funded by DG Research in the European Commission and comprised a consortium of institutions in 11 European countries and the United States.¹¹ It was established to explore the means to promote a broad societal debate, leading to proposals for responsible research and innovation (RRI) in neuroscience, specifically neuroenhancement (NE).

Allansdottir began with a definition of responsible research and innovation from the work of von Schomberg:

¹¹ Additional information is available at "Final Report Summary: NERRI (Neuro-Enhancement: Responsible Research and Innovation)." Available at https://cordis.europa.eu/result/rcn/192408_en.html (accessed September 4, 2018).

Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society). (von Schomberg, 2013: 19)

For the purposes of the workshop discussion, Allansdottir noted four key dimensions of RRI that were taken into account: anticipation, reflexivity, inclusiveness, and responsiveness (Stilgoe et al., 2013). “Anticipation” refers primarily to the preliminary stages of what has been termed “anticipatory governance” in the sense of actors involved in scientific and technological development collectively attempting to forecast the future trajectories of developments, including social, ethical, and legal aspects. In other words, what visions of society would potential developments of NE give rise to? “Reflexivity” refers to taking into account that all issues can have diverse and divergent framing. For example, particular developments in NE within a strictly medical context might take on a completely different framing and connotations outside that medical context. In other words, reflexivity imposes on those developing science and technology “to blur the boundary between their role responsibilities and wider, moral responsibilities” (Stilgoe et al., 2013: 1571). “Inclusiveness” implies going beyond consultations with stakeholders and shareholders in an attempt to invite wider society into a reasoned dialogue over a given issue or development. The NERRI project, along with other projects publicly funded by the European Commission, aimed to explore the way inclusiveness could potentially be reached in different cultures and countries and across segments of society. “Responsiveness” refers to how activities structured along the first three dimensions will lead to actual policy outcomes, that is, how the knowledge and experiences captured in the course of public engagement activities can be made relevant to policy makers and affect policy-making processes. She suggested that these dimensions should be considered as guidelines for work in progress.

As described by Allansdottir, NERRI built on the conceptual tools of mutual learning exercises in which experts and lay audiences discuss and learn from each other, as opposed to experts simply informing lay people about “facts” (Zwart et al., 2017). The project was inspired by the idea of decentralization, with the aim of including a wide variety of voices in a reasoned societal dialogue to make science and technology more relevant to society. Project partners conducted more than 60 events, bringing together a range of stakeholders and members of the public to discuss the feasibility, ethical acceptability, and social desirability of neuroenhancement. A variety of formats were used, from small discussion groups with a dozen selected participants to large open fora with hundreds of attend-

ees, from science cafés to activities in major exhibitions, and from theater plays to hands-on “hackathons” where enthusiasts engaged in NE design and development. Participants were always encouraged to contribute their own moral judgments and viewpoints.

The project focused on four areas of neuroenhancement: pharmacological, brain stimulation (Bard et al., 2018), gene modification (Gaskell et al., 2017), and an open-ended category of “other means.” Allansdottir indicated that the project did this in two different contexts. The first focused on employment and the second on education in all participating countries, and in this context raised questions: Was it acceptable to give children stimulants to increase their educational achievement? Would it be acceptable to take stimulants? Will NE help or hinder growing demands and pressures on the workforce? These initial questions were developed as the technology evolved and became contextualized. A small dedicated case study focusing on NE in the military context was carried out by partners from the United Kingdom and Italy. In the case of Italy, this followed a 2013 report that provided advice to the Italian government on cognitive enhancement and a second document on the use of human enhancement in the military context.¹² A preliminary workshop with military personnel used a vignette approach to stimulate discussion by presenting participants with a story to discuss from their own perspectives. The project team employed the following vignettes:

- Pharmacological stimulation: The protagonist is a pilot about to be deployed on a high-stakes mission.
- Neuroprosthetics: A soldier gets a “better” arm following an accident in order for him to return to combat.
- Moral enhancement: Empathy-enhancing drugs are used in interrogations of terrorist suspects and gathering of intelligence.
- Neural implants: In futuristic settings, implants allow military personnel to become more efficient and effective in combat.

She provided some elaboration on the neuroprosthetic vignette, presenting the story that was discussed in order to elicit the views of military

¹² Further information may be found at Italian Committee for Bioethics (Presidenza del Consiglio dei Ministri). Available at <http://bioetica.governo.it/en> (accessed September 4, 2018). Reports on “Human rights, medical ethics and enhancement technologies in military contexts” and “Neuroscience and pharmacological cognitive enhancement: bioethical aspects” are compiled in Presidenza del Consiglio dei Ministri Segretariato Generale. Italian National Bioethics Committee Opinions 2013–2014. Roma: Presidenza del Consiglio dei Ministri, Dipartimento per l’informazione e l’Editoria. Available at http://bioetica.governo.it/media/3518/9_opinions_2013-2014.pdf (accessed October 2, 2018).

personnel and stimulate thinking around issues that might not have otherwise been considered.

Allansdottir concluded with some reflections on the lessons from the NERRI experience. She indicated that such discussions can stimulate wider thinking, including around topics not previously given consideration. Other lessons from the project included the tendency toward “hype” rather than reality and the difficulties derived from the fact that NE is not a single technology but cuts across a range of domains of research that have implications for potential dual use. The distinction between restoration and enhancement, for example, is blurred, yet important. Public engagement was enlightening and necessary, but the project found that the wider public’s points of view diverge. She argued that established medical regulation is insufficient in the case of NE and that a more comprehensive governance framework is needed, and a fundamental rights approach might be considered. Finally, she noted that resilient governance should involve citizens and insights from the social sciences.

Discussion

The panel stimulated a number of questions, particularly around the Australian approach to export controls. One participant asked how the protocol for export controls was written and what happens if someone does not report an export. Others asked about feedback from the scientific community related to export controls and whether, for example, export licenses were required for speaking at a conference or applied to vaccine production. Others raised the issue of whether export controls on equipment, such as biosafety cabinets, were outdated.

Bowett provided a detailed response, indicating that they did not require scientists to obtain an export license to present at a conference, and that they had set the control threshold very high so the content of a PowerPoint presentation overseas would not be detailed enough to cross the threshold. Bowett reiterated the difficulties posed by export controls on intangible technology, highlighting the importance of outreach to deal with this and explaining how they engaged with universities and the circumstances in which researchers would need to come and speak with her organization. She indicated that it was very difficult to police emails, but through cooperation with colleagues in other government departments there was a legal route available to gain access to them if required. In relation to the question about vaccine production, Bowett noted that it was exempt from export controls if the vaccine was already developed or was going through certification. Pertaining to the question about biosafety cabinets, she noted that current control lists were a product of the Iran-Iraq war in the 1980s, and, although non-State actors do not necessarily

need 100-liter fermenters, such lists nonetheless provide a basis for talking to universities. Finally, Bowett indicated that the program issues about 4,000 permits per year, of which 350 permits are for the life sciences, and added that the vast majority of permits are not for intangible technology; in the past 3 years they have only had two intangible technology export requests in the life sciences area.

FOSTERING CHANGE

In addition to presentations on the concept of governance and examples of a range of governance activities, this workshop included presentations drawing on insights from the behavioral and social sciences to inform the participants' discussions of potential strategies and activities to enhance current approaches to the oversight of dual use research.

Coalface Governance: Fostering Daily Compliance in Laboratories

The first speaker was Ruthanne Huising of Emlyon Business School, a sociologist by training, who studied biosafety and security regulation and sought to translate her research into action at the working level. She argued that, based on her research and experience, improved compliance with regulations was needed. Making improvements required, in part, better understanding of both the way scientists and regulators interact in the workplace and of the challenges of translating normative codes and regulatory measures into action in laboratories.

Huising began with the example of how to get people to wear laboratory coats to illustrate some of the challenges of governance in real workplace settings, before relating this to the more sophisticated topic of dual use.

She outlined issues with compliance in academic laboratories, noting that most researchers' experience with compliance requests is as an intrusion on—and impediment to—their work (Gray and Silbey, 2014; Smith-Doerr and Vardi, 2015). Moreover, researchers often communicated safety measures as peripheral to core research work and delegated them to students and laboratory technicians (Huising and Silbey, 2013). She suggested that researchers will incorporate safety features into their practices when the features either align with efforts to control physical matter or help them do their research better (Bruns, 2009). There is variation in responses to regulation across disciplines. Chemists, for example, are in general significantly more accepting of regulation than biologists, and she attributed the differences to the fields' epistemologies, the tools used, and the ways chemists and biologists organized their laboratories. Huising commented that most violations are minor housekeeping prob-

lems but added that this should not mean violators are not held accountable since smaller violations can trigger bigger problems. She also noted that evidence suggests that a small number of laboratories account for the majority of violations (Basbug et al., 2016).

Huising then addressed the question of what was different about academic laboratories. Although corporate and diagnostic laboratories were generally doing quite well in terms of compliance, the structure of academic environments, the employment relationships, resources, rules and procedures, and work were different, at least from a North American perspective. In North American academic laboratories, PIs often have significant authority over their laboratories. Moreover, PIs report to their peers and department chairs; these are rotating positions, so there is a form of collegial governance in which, to some extent, the laboratories are regulating each other, rather than adopting the hierarchical model of decision making that was more commonly associated with corporate or diagnostic laboratories. Huising argued that the implementation of basic human resources policies is also different. In the academic context, implementation may vary considerably; for example, postdoctoral students are not employees of the laboratory, and laboratory membership is often rotating and determined by the PI. This contrasts with the corporate approach, in which the rules and procedures from the central human resources office that cover employees are followed much more consistently. Compared with corporate or diagnostic laboratories, academic laboratories also have less stability and cyclical resource flows, along with rules and procedures that are often quite localized and tacitly passed on through training. Moreover, in academic laboratories organizational-level rules were secondary, an important contrast with the corporate approach in which rules and procedures were developed at the organizational level in written form. The speaker also suggested that, in terms of the work processes and the expertise of personnel, academic laboratories tended to be more collaborative and open, with considerable variation across laboratories within the same institution.

Huising turned to discuss the roles of the professional bureaucracy and organizational cultures, suggesting that academics do not always respect bureaucracies. Yet, professional bureaucracies have significant implications for safety and security. They determine the responsibility for legal and administrative requirements, maintain the authority to enforce requirements (formally or informally), and hold control over the resources for compliance activities and equipment. Bureaucracies also represent allocations of authority over people working in laboratories.

In terms of organizational culture, she noted the increased attention to the topic by policy makers (Silbey, 2009). Organizational culture was seen as both a problem—"lax" or "insufficient cultures"—and a solution,

as evident in proposals for building a “culture of safety” or “changing the culture.” As such, organizational culture was understood by policy makers and managers as a tool to change and manage behavior. She suggested that the focus on change at the organizational level was overshadowing other important complementary levers to modify individual and collective behavior and reduce noncompliance in the laboratory setting (Huising and Silbey, 2018). One approach is the notion of “nudges,” which focus on relatively small changes that can nonetheless affect individual behavior and prompt improved compliance (Thaler and Sunstein, 2008). A second is “relational,” such as networks that can be developed to resolve logistical barriers to compliance that are often overlooked. A third approach is through the bureaucracy and bureaucratic process, such as written policies, placement of signs and reminders, the training of staff, and the inspection and correction regime. These important functions are usually sustained by professional staff, typically biosafety officers. The example of laboratory coats mentioned above illustrates how these complementary approaches could be applied. She noted that researchers not wearing laboratory coats in laboratories was a common infraction and something scientists openly admitted, in part, she suggested, because wearing them was perceived as a signal that the wearer was an amateur.

Beginning with nudges, she suggested that changes to choices about laboratory design or work routines, along with the placement of signs, messages, and personalized reminders, could be considered nudges intended to change how people think about simple compliance issues. More specifically, repositioning sinks or the location where laboratory coats were hung could affect whether people washed their hands and used their laboratory coats.

The second lever is the concept of “relational regulation,” which involves networks and teams that work beyond their official roles to understand compliance issues and craft local, pragmatic solutions (Huising and Silbey, 2018). She commented that there are numerous logistical issues tied to compliance. In the case of laboratory coats, the challenges include who supplies the coats, what type of coat should be worn, and who pays for, cleans, and replaces the coats. While these may seem like petty issues, they are nonetheless logistical barriers to compliance. Moreover, when identified, such issues are usually resolved by people who go beyond their formal roles, departments, and responsibility to solve the types of problems that often fall through the cracks. Such relational regulations are necessary to supplement bureaucratic means that often overlook such problems.

Huising stressed the importance of the role of techno-legal experts in organizations. Specifically, organizations depend on environment, health, and safety (EHS) staff (i.e., biosafety officers) to ensure compliance and

- walk researchers through record keeping, inspections, and corrections, and maintain compliance (Huisling, 2015);
- negotiate increased daily compliance by working in laboratories, generating familiarity, trust, and relationships; and
- anticipate problems and identify emerging dangers.

She indicated that these are the people who are able to walk past a laboratory familiar to them and swiftly determine if something is wrong. She also noted that these “boots on the ground” are chronically underfunded and experience challenges to their authority.

As the final lever, Huisling turned to organizational culture as one that should be supplemented. She explained the concept of organizational culture change as a conscious attempt to influence the action, language, thoughts, and feelings of employees. Changing organizational cultures can involve the promotion of values and norms reinforced through organizational rituals, symbols, language, stories, and other artifacts. However, she cautioned that culture change is both an expensive and long-term project, adding that anyone who wants culture change needs to secure the support of senior managers and sufficient funding. She also suggested that a key element of cultural change was determined by human resource practices and leadership.

Returning to the laboratory coat example, she commented that wearing laboratory coats was not common in promotional material for grant winners and questioned what message this sent to students. This reinforced her point that cultural change has to start at the top with those who control resources and seek to shape values and norms and to make decisions that align with those norms.

In her final comments, Huisling returned to her earlier point that a very small number of laboratories were particularly problematic and asked whether, although controversial, it may be time to start profiling them, noting that laboratories employing tenured staff and receiving funding windfalls were particularly prone to a large number of violations. She concluded by discussing the notion of “coalface” (i.e., front-line) governance and the importance of structural factors, noting that the distribution of authority and resources and the structure of employment have important implications for compliance. She suggested that, for the purpose of the governance of dual use research in the life sciences, multiple levers should be used simultaneously and recognition given to the central role for biological safety professionals. She also noted that it was important to understand the implications of biosafety professionals moving into the field of biosecurity.

Social, Behavioral, and Decision Science in Risk Management

Baruch Fischhoff of Carnegie Mellon University spoke on the role of social, behavioral, and decision sciences in risk management. He began by indicating that there were five different aspects of human behavior in risk management in this area:

- Biosafety—how materials are handled;
- Biosecurity—how other parties might use research, perhaps for nefarious purposes;
- Risk analysis—how one predicts the risks (and benefits), a human activity that is difficult to quantify;
- Risk management—how one addresses risks (and the missed benefits of not fully taking advantage of someone's science); and
- Risk communication—how one addresses others' concerns and manages the risks in a way that is perceived as appropriate.

Fischhoff argued that research has found that how people assess situations and the probability of things happening follows many simple principles. He gave several examples.

- People are good at tracking what they see, but not at detecting sample bias.
- People have limited ability to evaluate the extent of their own knowledge.
- People have difficulty imagining themselves in other visceral states.
- People have difficulty projecting nonlinear trends.
- People confuse ignorance and stupidity. (Presented by Fischhoff on June 12, 2018; Fischhoff, 2013: 14036.)

The speaker then outlined five examples of simple principles of choice emerging from the research:

- People consider the return on their investment in making decisions.
- People dislike uncertainty, but can live with it.
- People are insensitive to opportunity costs.
- People are prisoners to sunk costs, hating to recognize losses.
- People may not know what they want, especially with novel questions. (Presented by Fischhoff on June 12, 2018; Fischhoff, 2013: 14036.)

Fischhoff said that, while behavior follows some simple principles, the set of principles is large, the contextual triggers are subtle, and the

interactions are complex. As a result, broad knowledge and detailed analysis are needed to develop effective interventions.

In this regard, he noted the three-step design process followed by decision science. The first step, analysis, examines what decisions people face; the second step, description, examines how people currently make decisions; and the third step, the intervention phase, assesses how they can better make decisions based on the science. He noted that this was always an iterative process that was never right the first time.

Fischhoff commented that there are many real-world cases of applying the methodology drawing on this toolkit, including radon, preterm birth, climate change, phishing, and avian influenza. These had all been done in collaboration with subject matter experts who made sure participants in the design process were working around the same problem and “kept honest.” He noted that the insights provided by previous workshops of the U.S. National Academies on gain-of-function research for pathogens with pandemic potential (NASEM, 2016; NRC, 2015) and previous work on building communication capacity to counter pandemic disease threats (NASEM, 2017b) were particularly relevant to the governance of dual use research.

Fischhoff also identified three recommendations from an Institute of Medicine report on environmental justice (IOM, 1999) with implications for dual use governance: (1) improve the science base, to identify and verify environmental etiologies of disease and develop and validate research methods; (2) involve the affected populations, that is, engage with citizens from the affected populations in communities of concern, who should be actively recruited to participate in the design and execution of research; and (3) communicate findings to all stakeholders with an open, two-way process of communication.

In terms of human behavior in risk management, Fischhoff suggested there was good news because we can draw on more than a century of relevant basic science, with applications to many risks. The bad news is that, first, everyone is an intuitive behavioral scientist and has a theory about human behavior, so that actual science seems unneeded. In addition, many institutions lack not just internal expertise in behavioral research, but perhaps worse, lack what some economists call the “absorptive capacity” to obtain the needed expertise. Finally, he indicated that scientists may have perverse incentives, such as financial interests or those driven by personal interests and skills, that make them reject or ignore the insights behavioral science offers.

In terms of possible solutions, he suggested three bridging activities: the first was making relevant research available and accessible to those who would like to start a conversation; the second was creating general templates that could be adapted to local contexts; and the third was

establishing working relations that facilitate collaborative work. Fischhoff elaborated on each of these activities, beginning with making research accessible. He identified a number of sources of guidance for developing scientific communication (Fischhoff and Kadvany, 2011; Kahneman, 2011; Morgan, 2017). He also cited the U.S. Food and Drug Administration (FDA) text on communicating risks and benefits (Fischhoff et al., 2011) and the U.S. National Academy of Sciences Sackler Colloquia on the “Science of Science Communication,” which expanded the sphere of people addressing a particular topic¹³ and provided the basis for a major National Academies report (NASEM, 2017c).

Regarding the creation of adaptable templates as a solution, Fischhoff suggested that one approach was to develop protocols for consultative arrangements and presented an example for standard risk management processes (Fischhoff, 2015). These included a reality check at each stage, along with risk communication as a two-way process designed to make sure that people in the relevant communities were consulted and their views incorporated. He then noted work by Casman and others (2000) on the contamination of drinking water as a general model that could be applied to a variety of situations, as well as Bayesian approaches that could be used to improve the quality of the conversation even in the absence of quantitative variables (Fischhoff et al., 2006). The latter model, he suggested, could be applied to biosecurity and perhaps adapted to include differentiations among different sorts of scientists. He argued that adaptable templates could also be developed for risk-benefit communications, citing the *FDA Guidance on Communicating Risks and Benefit* (Fischhoff et al., 2011) as a useful source of information that summarizes the science, offers best guesses at practical implications, and shows how groups with different levels of financial resources can evaluate communications.

In terms of establishing working relations, Fischhoff presented examples of how this had been achieved in other domains, including intelligence analysis and cybersecurity, emphasizing the importance of creating a common language and drawing on an organizational model from behavioral science for these forms of collaboration (NASEM, 2017d;

¹³ Materials, including videos and links to related activities for the three colloquia in 2012, 2013, and 2017 may be found at National Academy of Sciences, “Arthur M. Sackler Colloquia: The Science of Science Communication.” Available at http://www.nasonline.org/programs/sackler-colloquia/completed_colloquia/science-communication.html; “Arthur M. Sackler Colloquia: The Science of Science Communication II.” Available at http://www.nasonline.org/programs/sackler-colloquia/completed_colloquia/agenda-science-communication-II.html; and “Arthur M. Sackler Colloquia: The Science of Science Communication III, Inspiring Novel Collaborations and Building Capacity.” Available at http://www.nasonline.org/programs/sackler-colloquia/completed_colloquia/Science_Communication_III.html. (accessed September 21, 2018).

NRC, 2011a). Such an organizational model requires basic familiarity with behavioral science and ongoing contact with behavioral scientists, as well as some in-house absorptive capacity.

Fischhoff concluded by discussing the FDA's strategic plan for risk communication and template for making risk-benefit decisions (FDA, 2013), noting the template had been developed through collaborative effort in a manner that drew from the behavioral sciences and employed design principles such as stakeholder engagement. He noted that this template was used in *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (NASEM, 2017e) and could be applied to other cases.

Discussion

The presentations stimulated a number of questions from the audience around several themes. One participant asked about the extent to which codes of conduct might stimulate cultural change beyond serving as a vehicle for transmitting messages. Huising responded that the evidence surrounding the effects of codes of conduct was mixed and that she was not familiar with any systematic research on this topic. Codes can make people feel good, which in itself may be transformative, but this was an area that requires further research.

Another participant asked whether risk perception was culturally specific and, looking beyond the focus on the United States, would risk perceptions be different elsewhere? Fischhoff responded that, generally speaking, *how* people think might be fairly similar across groups. However, what they believe and what matters to them likely varies much more.

Another participant asked Fischhoff about more formal risk-benefit analysis methodologies, to which he responded that risk analysis began as a design tool for looking at relative risks in circumstances where the overall safety level could not be assessed. Over time, this shifted to trying to estimate absolute levels of risk and benefit, even in situations where they cannot be meaningfully quantified.

A participant commented on the status of biosafety and EHS officers suggesting that they were not taken as seriously as academic researchers, and asked how one could increase the effectiveness of such individuals and their knowledge. Huising replied that with academic tenure came power, in contrast to others in staff roles who were apt to be ignored. However, she argued that there was scope for using knowledge and relationships with those in authority to get people to do things and exert influence in particular ways.

One workshop participant offered anecdotal evidence of his experi-

ence of top-down risk management following a workplace accident that totally changed the operation of the organization, triggering the release of resources and leadership from the highest levels that brought everyone into line. In another case, the participant outlined how he helped to address community concerns through the establishment of a citizens group with a rotating chair that allowed the community to become more closely involved in the conversation. Related to this, Huising dealt with a question about self-interest and situational reactions by drawing on her experience of group learning between the regulators and the regulated, something that, it was suggested, needs to be studied further.

The Current Governance Landscape

INTRODUCTION

The workshop encouraged active participation, with the majority of the workshop spent in smaller breakout sessions designed to facilitate discussion and take advantage of the expertise of those present. To support the discussions, staff of the U.S. National Academies of Sciences, Engineering, and Medicine (the National Academies) assembled two background documents that were provided to participants in advance of the meeting.¹ The first provided examples of relevant governance activities and actors and reflected the broad array of activities encompassed under the term “governance.” This included national, regional, and international laws, regulations, and policies, as well as efforts to develop and promulgate norms of responsible conduct, raise awareness about biosecurity and dual use concerns, and create educational materials. The second document provided examples of regional and international forums, organizations, or bodies that were or could become involved in dual use governance. The document reflected that, while there are bodies that address the topic, in particular the Biological and Toxin Weapons Convention (BWC), additional organizations and venues could offer valuable opportunities

¹ Special thanks to Tracy Kambara for assembling these materials and observations during her Mirzayan Science Policy Fellowship at the U.S. National Academies in spring 2018. We also wish to acknowledge contributions made by participants at a preliminary discussion held on May 18, 2018, at the U.S. National Academies, particularly to supplement information on the landscape of U.S. governance activities addressing dual use life sciences research.

to examine aspects of the current governance landscape and contribute to strengthening global governance of dual use life sciences research.

The two documents were intended to provide a starting point for discussions. Over the course of the workshop, participants were encouraged to suggest additional activities, venues, and ideas. Updated versions of the two documents reflecting those contributions may be found in Appendixes E and F as well as on the project website.² They provide a snapshot of examples of activities and actors in an effort to illustrate the range and variety of the current governance landscape. Reference links for the descriptive examples highlighted in this chapter are provided in these Appendixes.

BREAKOUT STRUCTURE AND PROCESS

Each breakout session was introduced by a plenary to outline its goals and procedures. Each breakout group had a chair and rapporteur, as well as a staff member from the U.S. National Academies to assist in collecting and collating the discussions. The rapporteurs reported the results of each breakout session back to the workshop participants, with time allotted for discussion during these plenary sessions.

Breakout Session #1

The goal of the first breakout session was to engage the participants in mapping the landscape of recent and current governance activities and contribute to building knowledge and awareness about the activities that have been conducted nationally and internationally. Because many participants had expertise in more than one type of activity or experience with more than one actor, the initial groups were encouraged to consider all aspects of governance. As illustrated in the opening plenaries and the background materials, multiple types of actors can carry out various activities. For example, codes of conduct can be developed by international and national scientific organizations, governments, industry associations, individual companies, or others. As part of the mapping exercise, participants were therefore encouraged to identify relevant actors as well as activities, with the lists below provided as a starting point.

² Available at National Academies of Sciences, Engineering, and Medicine, "Governance of Dual Use Research in the Life Sciences: An International Workshop." Available at <http://nas-sites.org/dels/events/dual-use-governance> (accessed September 4, 2018).

Types of Activity

- Laws and regulations for oversight of dual use research
- Multinational, regional, and international agreements and frameworks
- Policies and guidelines for oversight of dual use research (voluntary)
- Terms and conditions of funding
- Codes of ethics, conduct, and practice
- Education and engagement strategies and activities
- Technical advances/strategies to support governance
- Other

Actors

- National governments
- Multinational, regional, and international bodies
- Funders of life sciences research
- Scientists developing and conducting research (from academia, government, industry, etc.)
- Research performing institutions (such as universities and medical centers, industry, government laboratories, etc.)
- Journal publishers and others involved in disseminating research results
- Other

Breakout Sessions #2 and #3

Unlike the first breakout session, where participants were assigned randomly so they could address all of the topics in the background materials, for the second and third breakout sessions participants were assigned to groups based on their expertise and experience. The three topics were “Governance at the National Level;” “Governance at the Regional and International Level;” and “Promoting and Sustaining Governance—Norms, Codes, Education and Training, and Outreach.” The groups remained together for both breakout sessions, and each group addressed the same set of questions.

Building directly on the discussions in the first breakout session, in breakout session #2 the three groups were asked to consider the following questions:

- Lessons learned
 - What has worked well, what has not, and why?
 - Are there key lessons and good practices from these experiences?

- Are there particular areas of agreement and disagreement about the experiences to date?
- Gaps and meeting needs
 - Are there particular gaps and needs that, if addressed, could make a significant difference in the short and medium term for the development of effective oversight of research with dual use potential?
 - Are there enduring challenges and have strategies emerged to overcome or cope with them?
- Filling the gaps and needs
 - Who are the most important actors to fill the gaps and meet the needs? To carry out the strategies?
 - Are the key actors already engaged? If not, how can they be brought into the discussions/deliberations and where could these discussions/deliberations happen?
 - What resources would be needed (not just financial)?

The goal of the final breakout session was to identify opportunities to promote and sustain the governance of dual use life sciences research and concrete actions that could be undertaken in the short, medium, and longer terms to take advantage of these opportunities. It was recognized that participants may not agree on the most desirable actions and those differences of opinion were to be acknowledged. Participants were asked to address the following questions:

- Identifying opportunities and actions
 - What are the most important opportunities to promote and sustain the governance of dual use life sciences research? What concrete actions can be undertaken in the short, medium, and longer terms to take advantage of these opportunities?
 - Are there particular actions that, if taken in the short term, would contribute to the momentum for further development of governance?
- Recognizing obstacles and challenges
 - Are there key differences among participants about the most important or effective actions, and if so what are they? What are the sources of those differences? Are there areas of common ground or ways to work around those differences?
 - Thinking back to the discussions in breakout session #2, are there particular near-term gaps, needs, obstacles, or enduring challenges that will need to be addressed to take advantage of the opportunities?

- Moving toward action
 - Who are the most important actors to take advantage of the opportunities? To help overcome the obstacles and meet the challenges?
 - Are the key actors already engaged? If not, how can they be brought into the discussions/deliberations and where could these discussions/deliberations happen?
 - What resources would be needed (not just financial)?

THE CURRENT LANDSCAPE

The remainder of this chapter offers examples of the current governance landscape taken from the background documents and the discussions at the workshop in Zagreb and the special session in Washington, DC. The material provides an illustrative snapshot that is not intended to provide a complete accounting of actors and activities. That would be a substantial research task, although as several participants noted, the publicly available reports of States Parties to the BWC and of member states to the UN 1540 Committee provide significant amounts of basic information for those willing to undertake the search.

Fundamental Legal Norms

The current international regime for biological nonproliferation and disarmament rests on the 1925 Geneva Protocol, which bans the use of biological (and chemical) weapons, the BWC, which prohibits the development, production, and stockpiling of biological weapons, and United Nations Security Council Resolution (UNSCR) 1540, which focuses on preventing proliferation to non-State actors (UN Security Council, 2004). The BWC and UNSCR 1540 require the enactment of national legislation to support the implementation of their provisions. As of December 2016, for example, 152 countries had enacted legislation to prohibit the use of biological weapons by non-State actors in compliance with UNSCR 1540 (UN Security Council, 2016a: 16). In 2016, at the completion of a comprehensive review of the status of implementation of UNSCR 1540, the UN Security Council unanimously adopted Resolution 2325. This resolution “encourages States, as appropriate, to control access to intangible transfers of technology and to information that could be used for weapons of mass destruction and their means of delivery,” which provides greater potential to address dual use issues (United Nations, 2016b).

Countries may fulfill their obligations in different ways. In addition to any general legal prohibition, countries may enact legislation to address specific issues. As discussed further below, countries that undertake gov-

ernance of dual use research frequently undertake additional regulations and policies to supplement the legislation.

A limited number of countries explicitly reference “dual use” in the sense used during the workshop in their regulatory frameworks for the conduct of life sciences research. More commonly, efforts to address dual use issues draw on existing measures such as controls on access to and use of specific pathogens and toxins, regulations associated with genetically modified organisms, and export control regimes that apply to certain biological agents, equipment, and related technologies. This proceedings does not attempt to review national laws and regulations. Rather, examples in the chapter highlight a range of activities undertaken by governments, members of the scientific and civil society communities, and others to support the fundamental aims of such laws and regulations and to further the effective oversight of dual use research. How each country prohibits biological weapons and constructs the suite of legal and policy measures that provide for national security and research oversight varies, reflecting the legal traditions, experiences, and policy preferences of that country. Although no one size fits all, the BWC and UNSCR 1540, along with national implementing legislation and policy, provide a legal foundation and support the strong international norm against the misuse of advances in the life sciences.

GOVERNANCE ACROSS THE RESEARCH LIFE CYCLE

Governance of life sciences research that raises dual use concerns occurs across the full life cycle of a research project, from initial conception and planning of an experiment through the process of obtaining research funding, the conduct of the research, and dissemination of its results at conferences and in publications. In addition, activities associated with translation and commercialization of research, including patenting and licensing activities, can provide opportunities to implement governance measures. Table 3-1 highlights stages of the research life cycle and examples of governance activities associated with them. These categories do not necessarily have clear dividing lines, and relevant governance activities frequently apply to more than one phase. However, the stages of the research life cycle provide valuable opportunities to identify dual use concerns and to develop appropriate mitigation plans well in advance of research publication. As the table aims to make clear, governance of dual use life sciences research thus involves multiple stakeholders beyond government regulators and draws on a layered system of approaches, intervention points, and activities to help ensure appropriate and effective oversight. Illustrative examples of the types of efforts identified in the table are briefly described in the chapter sections that follow.

TABLE 3-1 Selected Examples of Governance Activities Across the Research Life Cycle

Examples of Activities That Cut Across the Life Cycle				
<ul style="list-style-type: none"> - National advisory boards on biosecurity, biosafety, and bioethics - Outreach conducted by national governments to relevant research communities - Systematic self-governance measures developed by a particular research community 				
Stages of the Life Cycle and Examples of Associated Activities				
Conception and Initial Project Development	Funding	Conduct of Research	Dissemination of Results	Translation and Product Development
<ul style="list-style-type: none"> - Safety and security awareness embedded in research planning - Institutional review committees - Technical approaches to risk mitigation 	<ul style="list-style-type: none"> - Proposal requirements and statements from research funders and sponsors 	<ul style="list-style-type: none"> - Risk mitigation plans implemented as a result of funder or institutional review - Training in laboratory risk management - Nucleic acid screening practices - Supportive institutional cultures 	<ul style="list-style-type: none"> - Statements and policies from journal editors - Export control regimes 	<ul style="list-style-type: none"> - Intellectual property, patent restrictions, licenses, material transfer agreements (not addressed in this report)

Cross-Cutting National Government Measures

A variety of efforts undertaken by national governments aim to promote governance of dual use life sciences research across multiple stages of the research life cycle. These efforts reflect the utility of approaches that can both provide targeted interventions for particular phases and support governance at more than one stage.

Advisory Bodies

As highlighted during the workshop, a number of countries make use of advisory bodies to provide input and guidance to government ministries and to the scientific community. Examples of national bodies tasked with addressing biosecurity issues include the following:

- *National Advisory Council for Biosecurity (France)*. Established by decree in 2015, the mission of the Council is to

... reflect on the potential misuse of life sciences and ways to protect against them. Serving public institutions or recognized to benefit the public with a research mission, the Academy of Sciences, or public authorities, it carries out prospective studies and monitoring activities surrounding dual use research in the field of life sciences. It proposes measures to prevent, detect, and counter possible threats. To this end, it formulates recommendations to ensure that biological science innovations do not generate new threats. It informs the public and strengthens the fields of science and health. Finally, it ensures the respect and improvement of international commitments.³

Half of the six members come from government agencies and half are nominated by the French Academy of Sciences.

- *Council for the Regulation of Research in Biological Pathogens (Israel)*. The legislation underpinning Israeli biosecurity policy, the Regulation of Research into Biological Disease Agents Act of 2008, was created in response to the report of the Steering Committee on Issues in Biotechnological Research in an Age of Terrorism, a joint project of the Israel National Security Council and the Israel Academy of Sciences and Humanities (Israel National Security Council and the Israel Academy of Sciences and Humanities, 2008). The 15-member Council, with a mix of technical experts from government ministries and academics from the fields of microbiology, infectious diseases, or biotechnology, advises the Ministry of Health on the implementation of the regulations.
- *National Science Advisory Board on Biosecurity (United States)*. The National Science Advisory Board on Biosecurity (NSABB), created in 2004 in response to the Fink report (NRC, 2004), is a federal advisory committee that addresses issues related to biosecurity and dual use research at the request of the U.S. government. Headquartered at the National Institutes of Health, “the NSABB has up to 25 voting members . . . [who] provide expertise in areas such as molecular biology, microbiology, clinical infectious diseases, laboratory biosafety and biosecurity, public health/epidemiology, health physics, pharmaceutical production, veterinary medicine, plant health, food production, bioethics, national security, biode-

³ See Le Conseil National Consultatif pour la Biosécurité. Available at <http://www.sgdsn.gouv.fr/missions/lutter-contre-la-proliferation/le-conseil-national-consultatif-pour-la-biosecurite-cncb> (accessed September 21, 2018). Translation by U.S. National Academies staff.

fense, intelligence, national security, law and law enforcement, recombinant or synthetic nucleic acid research, and export control. . . . In addition, the NSABB includes non-voting ex officio members from 15 federal agencies and departments.”⁴ Over the years it has produced a number of reports addressing dual use issues, most recently its recommendations for federal policy in response to the gain-of-function controversy (NSABB, 2016).

A number of national governments also make use of advisory bodies on biosafety and bioethics. Although not specific to concerns of dual use and biosecurity, such bodies help to promulgate safe laboratory practices, accepted standards of laboratory risk management, and norms of responsible conduct of research. The presence of these bodies and their activities also illustrates a point that arose during workshop discussions: although some countries address biosecurity as such, a number of other countries embed biosecurity considerations within a larger umbrella of biosafety or bioethics. This issue is discussed further in Chapter 4. Such a choice may meet the interests and needs of national scientific communities, reflect which ministries are in charge of particular topics (e.g., ministries of science or health versus ministries of defense), or arise from other national choices. Countries that have biosafety and bioethics bodies mentioned during the workshop include Malaysia, Singapore, and Ukraine.

Government Outreach to the Relevant Communities

A number of national governments have undertaken extensive outreach to their relevant scientific communities, addressing governance challenges and issues across the research life cycle.

- *Cooperation on Government Outreach (Kenya and Denmark).* The government of Kenya and many of its institutions have been active participants in biosecurity-related activities, such as capacity building for biosafety and awareness-raising activities, including dual use issues, for its scientific and health communities. One recent example is the project undertaken to raise awareness in Kenya’s universities about the need for increased laboratory biosecurity. The terrorist attack at Garissa University in 2015 called attention to the vulnerabilities of laboratories that conduct research or house collections of pathogens. A partnership among two Kenyan government departments (the National Commission for Science,

⁴ See NSABB FAQ Question 4. Available at <https://osp.od.nih.gov/biotechnology/nsabb-faq> (accessed October 3, 2018).

Technology and Innovation [NACOSTI] and the Commission for University Education) and the Danish Centre for Biosecurity and Biopreparedness led to the “Kenya National Biosecurity Workshop for Universities” in January 2018. NACOSTI is the National Focal Point to the BWC and the UN 1540 Committee, so the workshop reflected “NACOSTI’s role in coordinating the whole-government implementation of nonproliferation of biological weapons” (Amunavi, 2018).

- *Department of Defence Export Control Branch (Australia)*. As discussed in Chapter 2, the Australian government’s approach to export controls places great emphasis on outreach, and the Life Sciences Guide was developed through outreach and consultations with the life sciences sector to inform and assist Australian life scientists (Australian Government Department of Defence, 2016). The Guide uses real-life scenarios to explain export control requirements and exemptions. This is complemented with considerable outreach activities directed at universities, public health networks, and companies, including the use of a capital city roadshow to key cities in Australia, the appointment of export control managers at relevant facilities that serve as single points of contact, the development of a toll-free export control helpline, and frequent presentations at relevant conferences and expos. The Guide has been shared with members of the Australia Group as a potential model to be adapted for use in other countries.
- *Biosecurity Office (The Netherlands)*. The Biosecurity Office, part of the Dutch government’s response to the gain-of-function controversy, has conducted a variety of education and outreach activities. The Office has hosted workshops that brought together various stakeholders (universities, medical centers, industry, veterinarians, plant scientists, etc.). “Toolkits,” self-assessment surveys that can help to identify biosecurity strengths and weaknesses within an organization, are available on its website.⁵ There is also a 5-minute movie on the “8 pillars of biosecurity.”

Systematic Self-Governance

A number of European countries undertook measures in response to the pathogen gain-of-function controversy (see NASEM, 2016; NRC, 2015). The initiative for the systematic self-governance effort undertaken by the German scientific community in response to the potential for fur-

⁵ See Bureau Biosecurity, “Toolkit.” Available at <https://www.bureaubiosecurity.nl/Toolkit> (accessed September 21, 2018).

ther government oversight actions is one example. At the request of the German government, the German Ethics Council undertook a review of whether the current legal framework and the codes of conduct being used in the academic and private sectors provided an adequate foundation for making decisions about funding for such research. The report of the Council made a comprehensive set of recommendations that addressed the actors, institutions, and instruments that could govern the research in the future (German Ethics Council, 2014: 179).

The German scientific community undertook a number of initiatives aimed at supporting and strengthening research governance. The German Research Foundation (DFG) updated its *Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins* to ensure that it remained valid in light of the advances in genome editing and synthetic biology (DFG, 2013). The DFG and the German National Academy of Sciences Leopoldina also developed an alternative governance arrangement based on self-governance by the research community rather than additional regulation. Building on the report of a joint DFG-Leopoldina committee (DFG and Leopoldina, 2014), they appointed an interdisciplinary and cross-institutional committee to implement the report's recommendations and oversee the creation and guidance of Committees for Ethics in Security-Relevant Research (KEFs) at research institutions. The committee produced a set of model statutes that provides guidance for setting up and operating the KEFs and that ensures uniformity across different institutions.⁶ At the time of the Zagreb workshop, more than 70 institutions had created KEFs (German Government, 2018). The German government considers the self-regulatory approach a first step and will await the outcome of this effort before reevaluating any need for legislation regarding biosecurity and dual use.

Activities Associated with Initial Research Conception and Planning

Principal investigators have a general responsibility to design experiments to meet ethical, legal, and institutional standards and to plan for their safe conduct, as do the research-performing organizations and institutions where such research occurs. Thus, the governance of life sciences research that may raise dual use concerns begins with the initial stages of developing a research project.

⁶ Further information is available at German National Academy of Sciences Leopoldina. Available at <https://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use> (accessed October 2, 2018) and in the paper presented by the German government at the 2018 Meetings of Experts (German Government, 2018).

Awareness of Potential Concerns

An important first step in identifying that a proposed experiment or project may raise dual use concerns is the researcher being aware that there may be benefits and risks to evaluate or biosecurity concerns to consider that go beyond traditional biosafety issues. Members of some research communities, such as investigators working with pathogens with pandemic potential or those on the “Select Agents” list, are likely to have greater awareness of security than investigators from communities that have engaged far less frequently with safety and security issues. On the other hand, even with awareness, disagreements about the potential risks posed by a line of research may remain; one of the researchers whose work sparked the influenza “gain-of-function” debates in 2011, for example, had served on the Dutch academy committee that drafted its biosecurity code of conduct. Decisions on when benefits outweigh risk or when adjustments to a research plan are warranted to mitigate concerns are not always clear-cut. A subsequent section of the chapter addresses awareness-raising efforts and education in more detail. In addition, examples of training on laboratory risk management practices are covered under the “conduct of research” phase below.

Institutional Review Committees

An institutional oversight committee such as an Institutional Biosafety Committee (IBC) is a mechanism used in many parts of the world to oversee the appropriate conduct of research. Participants who believed in a strong nexus between biosafety and biosecurity, for example, would be likely to prefer making use of an arrangement grounded in biosafety to also now address biosecurity issues. Investigators provide information to IBCs and other institutional oversight committees (such as Institutional Review Boards, Institutional Animal Care and Use Committees, and others) to describe research they plan to conduct and to demonstrate that they have considered how to address issues or concerns it may present. In the United States, an additional type of institutional committee, an Institutional Review Entity (IRE), may be involved in the assessment of whether a research project poses dual use concerns. To comply with U.S. policies on Dual Use Research of Concern (DURC), proposals that involve particular types of research on specific agents and toxins are referred to the institution’s IRE for further review. Although U.S. DURC policies require institutions to examine research on 7 types of experiments and 15 agents, Kanabrocki’s presentation illustrated that a number of universities use their investigator, IBC, and IRE structures to survey proposed research more broadly than required in order to evaluate whether research poses biosecurity concerns and to consider whether additional risk mitigation

plans are needed. However, not all research that could potentially pose dual use issues for the life sciences, such as in engineering or computer science departments, is likely to be captured by these review committees.

Embedding Safety and Security into Research Planning: Example of iGEM

Through its annual competition and other programs, the International Genetically Engineered Machine (iGEM) Foundation now reaches thousands of high school and undergraduate students interested in synthetic biology. To educate participants in appropriate research design and to address safety and security concerns, iGEM maintains a Safety and Security Hub with information on its policies in areas such as organisms with which teams can work and tools to aid in assessing a project's risk.⁷ Teams must also complete a safety and security form on their proposed project. Although the program is primarily directed toward student researchers, it represents a case example in which security and risk considerations are embedded into the initial stages of research conception and planning.

Technical Approaches to Risk Mitigation

In some cases, it may be possible for investigators to change the design of an experiment or to incorporate other technical safeguards into their research to help mitigate dual use and biosecurity concerns; such approaches represent an opportunity to implement technical strategies to support research governance. For example, an investigator could choose to conduct an experiment with a modified or less pathogenic strain of a microorganism. Other examples include engineered auxotrophy, in which a molecule necessary for an organism's growth must be provided in the laboratory, or strategies in which gene expression is induced only in the presence of a specific substance. The Safe Genes program through the U.S. Department of Defense's Defense Advanced Research Projects Agency illustrates also this concept for one approach to genome editing. Safe Genes supports the development of "tools and methodologies to control, counter, and even reverse the effects of genome editing—including gene drives—in biological systems across scales;" these approaches are in the early stages of development.⁸ Types of strategies investigated through the program include the ability to inhibit or block genome editing activity in an organism (for example, with genome editors whose activity is

⁷ Available at iGEM, "Safety and Security Hub." Available at <http://2018.igem.org/Safety> (accessed September 4, 2018).

⁸ See DARPA, "Safe Genes." Available at <https://www.darpa.mil/program/safe-genes> (accessed September 4, 2018).

regulated by the presence or absence of certain molecules), to reverse genome editing to restore a previously edited genome to its initial state, or to design gene drives that are limited in their number of generations and thus have a reduced ability to spread uncontrollably. Where scientists are able to incorporate strategies that improve control or reversibility into genetic engineering research from initial planning stages, such efforts could help prevent misuse or mitigate negative effects in organisms and environments, supporting risk management, biocontainment, and biosecurity goals.

Activities Associated with Funding

Since the early 2000s when concerns about potential risks from research with dual use potential arose, a commonly raised point is that waiting until the stage of journal publication is far too late in the process to be introducing debates over whether a particular research effort should be disseminated. Ideally, such research could be identified much earlier and additional procedures or safeguards implemented as necessary. The funders of life sciences research have considerable leverage to request that scientists applying for support consider dual use issues, to require the adoption of procedures to mitigate concerns, or to require that adjustments to research plans be made as conditions of funding. Thus, the funding stage has become an important opportunity to support governance and oversight. Several funders have created or expanded dual use proposal review systems in recent years.

- *Ethics Self-Assessment Under the European Commission (EC)*. In its oversight of research under the Horizon 2020 program, the European Commission maintains a distinction between traditional dual use research and what it terms research that “involves materials, methods or technologies or generates knowledge that could be *misused for unethical purposes* (emphasis added). Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment” (European Commission, Undated: 1), which corresponds to the concept developed in the Fink report (NRC, 2004). A researcher applying for funding addresses questions of whether his or her research has the potential for misuse as part of the mandatory Ethics Self-Assessment that is part of the proposal process. As an EC guidance note explains:

If you are planning research that may give rise to concerns about potential misuse, you will need to do the following when preparing your proposal:

- tick the box in the ethics table in part A
- provide a risk-assessment in part B and explain how you will prevent misuse
- if required, attach copies of authorisations, security clearances, and ethics approvals

Describe in the risk table in the management section what action you would take if the national authorities do not grant authorisation (European Commission, Undated: 2).

- *Grant Requirements of the Medical Research Council/Biotechnology and Biological Sciences Research Council (BSBRC)/Wellcome Trust.* In 2005, the three major funders of life sciences research in the United Kingdom, two government and one private, introduced a joint requirement that grant applicants and reviewers address potential dual use risks of proposed research. In 2015, partly in response to the gain-of-function controversy, the three funding bodies revised and updated the statement (BBSRC et al., 2015). The new statement adopts a focus on DURC rather than dual use,⁹ but asserts that “we as research funders must take a proactive lead” (BBSRC et al., 2015: 5). It retains the expectation that researchers, research-performing institutions, and the research community more broadly have responsibilities across the full life cycle of research to address potential risks of misuse. The statement also endorses education and training to enable researchers to fulfill these responsibilities effectively. The statement includes specific guidance for reviewers and applicants and expresses support for an approach based on self-governance by the scientific community, noting that “Effective self-governance requires the research community to take clear and proportionate steps to ensure the risks of dual use research of concern are identified and addressed appropriately where they arise” (BBSRC et al., 2015: 5).
- *Processes in Use by Other National Funders.* The main government research funding agency in Croatia, the Croatian Sciences Foundation, requires applicants to provide information concerning ethics and dual use issues when submitting project proposals. The self-governing organization for science and research in Germany, the DFG, which receives the large majority of its funds from the federal government and has the federal states represented in all grants com-

⁹ The statement notes that “other types of potentially harmful misuse of research exist, such as risks of research findings being used to stigmatise or discriminate against particular population groups” and “It is also important to note that these risks are by no means exclusive to research which directly involves the use of hazardous agents, and are not restricted to misuse for terrorist purposes” (BBSRC et al., 2015: 1).

mittees, has established a procedure for reviewing research proposals with dual use potential. Principal investigators must address the presence of dual use in their research and reviewers will then assess and make recommendations before funding is approved.

- *Funding Reviews Under U.S. Government Policies.* The U.S. government has a series of sometimes overlapping policies and regulations to provide oversight of dual use research. The 2012 and 2014 DURC policies apply to 15 agents and toxins and 7 categories of experiments. The 2012 policy requires all federal agencies that fund life sciences research to review their portfolios regularly to identify any DURC and assess potential risks, working with researchers to develop risk mitigation plans as necessary (U.S. Government, 2012). The 2014 policy sets out specific obligations of researchers and research-performing institutions that are consistent with the 2012 policy on government funding (U.S. Government, 2014a). As the culmination of the U.S. government's deliberative process for gain-of-function research, in January 2017 the White House Office of Science and Technology Policy issued its *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (U.S. Government, 2017), which applies to any agents that meet certain criteria rather than to a predefined list. In December 2017 the U.S. Department of Health and Human Services released its policy for review of proposed funding for research on enhanced potential pandemic pathogens consistent with the 2017 OSTP guidance (HHS, 2017). The policy updated and expanded an earlier 2013 funding review process for certain H5N1 influenza experiments (HHS, 2013), maintaining the interagency review process, while replacing the previous policy's limitation to specific agents with the criteria-based definition from the 2017 OSTP guidance. The HHS policy also provided criteria to guide funding decisions and a review and oversight framework. As of the time of this report, this was the only federal agency to have adopted a specific policy for pathogens with pandemic potential.

The funding policies cited above are all either from governments or private foundations. Depending on the country or region, the percentage of research supported by these sources can vary significantly. Over the years, the funding landscape has diversified so that, particularly in developed countries, it now includes private industry, crowdsourcing, charitable organizations other than foundations, venture capital, and foreign investors and funders. Depending on the circumstances, this diversity of funding sources can be a challenge for the use of funding as a lever for research oversight.

Activities Associated with Conduct of Research

A number of the case examples highlighted in background materials and during the workshop featured governance measures applicable to the conduct of research. These include the implementation of risk management plans for research that raises dual use concerns, as well as awareness-raising and technical training on safety and security best practices for such research. An important component recognized during the workshop is the role of organizational culture in helping to ensure that safety and security considerations are seen as more than “check the box” compliance activities.

Research Oversight and Risk Mitigation

As noted in the preceding sections, both research funders and institutional review committees may identify potential biosecurity concerns arising from proposed research projects and request that experimental procedures be adjusted or risk mitigation plans developed and implemented to address such issues. In the United States, for example, federal DURC policies require agencies that fund life sciences research to work with the researcher or research-performing institution to develop a mitigation plan to address any identified risks (U.S. Government, 2012, 2014a). The European Commission and UK funding policies described above have similar provisions for the development and implementation of risk mitigation plans. Provisions requiring regular reporting and immediate reporting of unexpected results that could pose new or increased dual use risks reflect the recognition that it may not be possible to predict the outcomes of research at the funding stage.

Other countries may use approaches such as research licensing and institutional inspections to oversee the conduct of life sciences research that raises dual use concerns.¹⁰ In Denmark,¹¹ for example, the Centre for Biosecurity and Biopreparedness (CBB) is responsible for implementation and has a variety of means to secure dual use technology.¹² Public and

¹⁰ The U.S. Select Agent Program, which is based on formal regulations, also has licensing, personnel reliability, and inspection provisions, but other U.S. policies for dual use do not. Additional information may be found at <https://www.selectagents.gov> (accessed September 4, 2018).

¹¹ The legislative basis for biosecurity in Denmark is the 2008 Act on securing biological substances, delivery systems, and related materials (Act no. 474 of June 2008), with additional authorities under the Executive Order on securing specific biological substances, delivery systems, and related materials (EO no. 981 of October 15, 2009, with Updated Annex 1 to EO 2017 [under Related Materials section j]).

¹² Dual use research is treated under the Executive Order and is generally referred to as “technology with dual-use potential” or “dual-use technology.”

private laboratories that intend to work with controlled materials must file an application for a license to do so. In the application, they must also assess whether they have any dual use technology, which will be checked by CBB during inspections. Inspections may also be carried out in institutions and companies without a license from CBB, but which have research activities that suggest dual use technology potential. If inspections indicate that the companies conduct research that is deemed to have misuse potential, the organization or company must apply for a license from CBB. Spot checks and screening of publications are also conducted on a regular basis. If dual use technology is detected the company is categorized according to the risk potential and must obtain a license to continue its research activities and/or receive mandatory guidance and advice from CBB. Violations could result in fines or imprisonment.¹³

Criteria for Assessing the Dual Use Potential of Research

The Robert Koch Institute (RKI), a federal institute within the portfolio of the Federal Ministry of Health, is the German government's central scientific institution in the field of biomedicine and the national public health institute. The Institute has developed and adopted a code of conduct for risk assessment and risk mitigation that is obligatory for employees of RKI. In addition to basic principles intended to reduce the potential for dual use risks, the code provides criteria for assessing the dual use potential of research projects and their results, as well as additional information on the research project and risk assessment evaluation to be conducted, including steps to mitigate any risks identified and the points during research at which evaluation must occur. RKI also plans to raise awareness through seminars and training (RKI, 2013).

Biosafety Associations and Capacity Building in Biosafety

Many consider biosafety to be the essential foundation for biosecurity, including oversight of dual use research. Substantial effort has gone into capacity building for individuals and institutions around the world, reflected in the growth of biosafety associations since the early 2000s. The International Federation of Biosafety Associations (IFBA) is a global not-for-profit nongovernmental organization whose members include national and regional associations. Its 33 national association members, from developed and developing countries, cover the globe, and regional

¹³ Available at Centre for Biosecurity and Biopreparedness, "How to Apply" and "Technology." Available at <https://www.biosecurity.dk/526> and <https://www.biosecurity.dk/689> (accessed September 4, 2018).

associations include Africa, the Asia-Pacific, Central Asia and the Caucasus, and Europe.¹⁴

Training and Professional Certification for Biorisk Management and Biosafety Professionals

IFBA “has launched a new certification program for biorisk management and biosafety professionals worldwide. . . . An IFBA certificant is an individual who has met the eligibility requirements and achieves acceptable performance levels on examinations. The IFBA certifies individuals at the ‘Level 1 – Professional Certification’ and ‘Level 2 – Specialist Professional Certification’ in a number of specializations and technical disciplines related to the field of biosafety, biosecurity, and biorisk management. Certifications are valid for a period of 5 years and require ongoing maintenance demonstrating active upgrading of skills and participation in the profession.”¹⁵

Changing Organizational Culture in Support of Biosecurity

The talk by Ruthanne Huising described in Chapter 2 lays out some of the challenges and options for achieving change in the ways that organizations operate, from specific practices to broad “culture.” In 2014, a series of significant lapses involving the handling of pathogen inventories at federal laboratories in the United States led to a substantial effort to assess and improve biosafety and biosecurity. The White House ordered any federal laboratory that shipped or worked with infectious plant or animal agents or toxins to carry out a “Safety Stand-Down” to review its practices and protocols (Kaiser, 2014). The White House also tasked the Federal Experts Security Advisory Panel (FESAP) to

- 1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT; 2) identify actions and any regulatory changes to improve biosafety and biosecurity; and 3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT [Biological Select Agents and Toxins]. (U.S. Government, 2014c: 3)

¹⁴ The list of members is available at IFBA, “Member Associations.” Available at <https://www.internationalbiosafety.org/index.php/ifba-members/ifba-membership/member-associations> (accessed September 4, 2018).

¹⁵ See IFBA, “About the Program.” Available at <http://www.internationalbiosafety.org/index.php/professional-certification/ifba-professional-certifications/about-the-program> (accessed September 18, 2018).

Based on that report and additional interagency reviews, in 2015, the White House announced a comprehensive plan to implement the recommendations, which included efforts to “Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences” (U.S. Government, 2015: 1). Interagency work to develop and implement training to achieve appropriate cultural change continues.¹⁶

Screening Orders for Research Materials

Controls may also be implemented around access to certain types of research materials. For example, many life sciences research projects make use of commercially acquired DNA sequences. In 2010 the U.S. government produced *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* (HHS, 2010). The industry has developed its own guidance through the International Gene Synthesis Consortium (IGSC). Initially established in 2009 and incorporated in the United States in 2015, the members of the IGSC represent about 80 percent of current gene synthesis screening capacity internationally. The Consortium’s original 2009 protocol was updated in 2017 to the Harmonized Screening Protocol © v2.0. “By uniformly screening the sequences of ordered genes and vetting gene synthesis customers, IGSC members collaborate to establish and continuously improve best practices, safeguard the many benefits of gene synthesis technology while minimizing risk, and help ensure broad compliance with HHS Guidance for Double-Stranded DNA Providers and other international standards” (IGSC, 2017: 1).

Activities Associated with Dissemination of Results

The results of research efforts are publicized in conferences, made available in prepublication form on preprint servers such as bioRxiv,¹⁷ and published in numerous scientific journals. Controversies over the publication of articles containing the results of dual use research in the life sciences became particularly intense in the early 2000s amid rising concern about terrorists’ interest in acquiring weapons of mass destruction. As a result, a number of groups involved in scientific publishing have addressed biosecurity or recommended policies on research publication.

¹⁶ Additional information is available at U.S. HHS, “Federal Experts Security Advisory Panel (FESAP).” Available at <https://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx> (accessed September 4, 2018).

¹⁷ See Cold Spring Harbor Laboratory, “bioRxiv.” Available at <https://www.biorxiv.org> (accessed September 4, 2018).

Journals including *Science*, *Nature*, *PLOS*, and the journals published by the American Society for Microbiology have dual use review policies. In addition:

- *Journal Editors and Authors Group*. At the urging of the American Society for Microbiology and others, the U.S. National Academy of Sciences and the Center for Strategic and International Studies organized a one-day public meeting of publishers, scientists, security experts, and government officials in January 2003 to explore the issues and discuss potential actions that could address the concerns. The following day a group of journal editors, along with invited scientists, officials, security experts, and others held a separate private meeting. On the basis of the discussions and further consultations, a “Statement on Scientific Publication and Security” by the Journal Editors and Authors Group was published in *Science*, *Nature*, and the *Proceedings of the National Academy of Sciences* from February 18 to 21 (Journal Editors and Authors Group, 2003). The statement offered principles to guide scientists and journal editors in devising processes for reviewing and managing the dissemination of dual use research.
- *White Paper on Promoting Integrity in Scientific Journal Publications from the Council of Science Editors*. The Council of Science Editors (CSE) is an international membership organization whose aim is to be “an authoritative resource on current and emerging issues in the communication of scientific information.”¹⁸ Since 2006 CSE has published a *White Paper on Promoting Integrity in Scientific Journal Publications*, which is periodically revised and, beginning in 2018, will be added to and updated on a rolling basis to keep pace with new information and best practices. The most recent guidance regarding dual use research states that “Editors can educate journal boards, reviewers, and authors; establish screening methods to recognize DURC; obtain reviews of these manuscripts from individuals with technical and security expertise; and create an ongoing network to share experiences and further refine ways for managing DURC. Editors should develop guidelines and procedures to allow the scientific evaluation as well as the evaluation of the possible risk of communicating information with dual use potential” (Council of Science Editors, 2018: 7).

¹⁸ See Council of Science Editors, “About CSE.” Available at <https://www.councilscienceeditors.org/about/about-cse> (accessed October 2, 2018).

Activities Associated with Product Development and Translation

As noted in Chapter 2, the private sector is a stakeholder in addressing dual use research, whether as funders and investors in research, as organizations that conduct research and development, or as organizations that license or translate research into products. Governance of life sciences developments can be implemented at these later stages of the research life cycle. For example, conditions placed on the acceptable uses of intellectual property through patent licenses and material transfer agreements can function as governance mechanisms and may have applicability to dual use research. The workshop did not focus on engagement with the private sector to advance life sciences governance or discuss such mechanisms in detail. This remains an area in which future work or further discussions may be useful.

PROMOTING AND SUSTAINING GOVERNANCE

As discussed frequently during the workshop, effective governance requires more than “check-box” compliance with regulations, policies, and practices. Acceptance and engagement by the affected communities are essential and this requires sustained and continuing effort. Governments may play a role in fostering and promoting governance, while self-governance depends on the actions of the affected communities themselves. The scientific community frequently asserts its capacity to govern itself with regard to key aspects of the conduct of research, including dual use issues. This section provides examples of some of the activities that can promote and sustain governance (see Table 3-2).

Foundational Principles: Norms on the Responsibility of Science and Scientists

The responsibility of the scientific community to consider social and ethical issues beyond the conduct of science itself, including the possibility that research could be misused to cause harm, has been addressed by several global scientific bodies. These influential statements help to establish the foundation for acceptable behavior and for what it means to be a responsible member of the scientific community:

- *Freedom, Responsibility, and Universality of Science* from the International Science Council (ISC). Published by the Council’s Committee on Freedom and Responsibility in the Conduct of Science (CFRS) in 2014, this publication discusses both the norms of scientific freedom and the responsibilities of science and individual scien-

TABLE 3-2 Selected Examples of Activities That Promote and Sustain Governance

Types of Activities	Examples
Norms for Responsible Scientific Conduct	- International Science Council (ISC) ^a - United Nations Educational, Scientific and Cultural Organization (UNESCO)
Principles for Biosecurity	- InterAcademy Partnership (IAP) - Hague Ethical Guidelines
Codes of Ethics and Conduct	- Codes developed and promulgated by multiple international and national organizations
Awareness Raising and Outreach	- Croatian Society for Biosafety and Biosecurity - Moroccan Biosecurity Caravan
Education Programs	- Danish Centre for Biosecurity and Biopreparedness - Dual Use Education in Pakistan - European Union engagement efforts under Project 18 - Responsible Science Institutes (United States)
Educational Materials	- Module from Academy of Sciences Malaysia - Resources developed by Bradford University - Case studies from the Federation of American Scientists
Networks and Clearinghouses	- UN Interregional Crime and Justice Research Institute (UNICRI)

^a This is the new name of the organization formed in 2018 by the merger of the International Council for Science (ICSU) and the International Social Science Council (ISSC).

tists.¹⁹ One of the broad statements of principle in the document is that “Science depends on society’s respect for its processes and support for its activities. It is widely acknowledged that there is an informal, social contract between science and society. This contract implies certain responsibilities from society to science, and from science to society” (ICSU, 2014: 4). With regard to potential misuse and individual responsibility, the publication states that, “Given this potential for multiple-use, the demands on scientists to pay careful attention to their individual and communal responsibilities are higher than in many other areas of work. Scientists have

¹⁹ ICSU established the CFRS in 2006. “This Committee differs significantly from its predecessors that, since 1963, had focused on scientific freedom, in that it is explicitly charged with also emphasizing scientific responsibilities” (ICSU, 2014: 3).

an obligation to critically reflect upon how their expertise is used, particularly when asked to support decision-making and policy processes" (ICSU, 2014: 17).

- *Recommendation on Science and Scientific Researchers from UNESCO.* The document, adopted by the UNESCO General Conference at its 39th meeting in 2017, lists responsibilities and freedoms of individual researchers, institutions, and funding agencies. Researchers have a responsibility "to express themselves freely and openly on the ethical, human, scientific, social or ecological value of certain projects, and in those instances where the development of science and technology undermine human welfare, dignity and human rights or is 'dual use', they have the right to withdraw from those projects if their conscience so dictates and the right and responsibility to express themselves freely on and to report these concerns" (UNESCO, 2017). A report on member states' progress in implementing the recommendations is to occur every four years, starting in 2019. The Annex, which contains a list of other conventions, recommendations, and initiatives, is a helpful resource for self-governance. The UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) also provides a potential forum for further discussions of dual use and biosecurity.

Codes of Ethics and Conduct as a Strategy for Addressing Biosecurity and Dual Use

Efforts aimed at providing ethical guidance for the scientific community focused on biosecurity and dual use build on this more general framework of scientific responsibility. Discussion, development, and promulgation of biosecurity codes of ethics and codes of conduct²⁰ have been one of the most commonly undertaken global governance activities, with a number of examples from different sectors of the scientific community and from multiple countries provided below.

²⁰ Rappert makes a widely used distinction: "aspirational codes (often designated as 'codes of ethics') set out ideals that practitioners should uphold, such as standards of research integrity, honesty, or objectivity. . . . Educational/Advisory codes (often designated as 'codes of conduct') would go further than merely setting aspirations by providing guidelines suggesting how to act appropriately. . . . and 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" (Rappert, 2004: 14–18).

Principles to Be Used in Developing Codes

One approach taken by international scientific and ethics communities has been to develop a set of principles for addressing biological and chemical security concerns, rather than a “code” itself. This approach is motivated by a desire to enable common understanding of the broad aspects that should be encompassed by codes, while the translation of these principles into more specific provisions is undertaken by scientific disciplines or at national or institutional levels. That enables the principles to be reflected in ways that are most suited to the scientific needs and legal and regulatory frameworks of the local context and, it is hoped, increases the sense of “ownership” by those the codes are intended to influence. Two examples reflect the idea of developing principles focusing on security concerns:

- *Statement on Biosecurity from the InterAcademy Partnership (IAP)*. The Statement, developed for the 2005 discussions at the BWC, sets out five guiding principles that should be considered for inclusion in codes of conduct: awareness, safety and security, education and information, accountability, and oversight. Researchers should “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 endeavor” (IAP, 2005).
- *The Hague Ethical Guidelines*. The Organisation for the Prohibition of Chemical Weapons (OPCW) is the organization that administers the Chemical Weapons Convention, the international treaty prohibiting the use of chemicals in warfare. In 2015 the organization supported the development of principles aimed at “Applying the norms of the practice of chemistry to supporting the Chemical Weapons Convention.”²¹ The Guidelines have been translated into the six official languages (Arabic, Chinese, English, French, Russian, and Spanish) and endorsed by chemistry organizations from academia and industry, including the International Union of Pure and Applied Chemistry and the International Council of Chemistry Associations. In creating the principles, the scientists meeting under OPCW’s auspices collected and analyzed more than 140 codes of ethics and conduct relevant to chemistry—highlighting how many codes already exist, many of which may have common

²¹ See Organisation for the Prohibition of Chemical Weapons, “Ensuring an Ethos of Science for Peace: The Hague Ethical Guidelines.” Available at <https://www.opcw.org/special-sections/science-technology/the-hague-ethical-guidelines> (accessed October 2, 2018).

underlying elements. The Ethical Guidelines articulate nine key elements: a core principle that “chemistry should be used to benefit humankind and to protect the environment,” along with sustainability, education, awareness and engagement, ethics, safety and security, accountability, oversight, and exchange of information. The principles are intended to enable stakeholder engagement in taking ownership of translation into codes, along with recognition that codes will need to be adaptable and evolve over time. Thus, the Ethical Guidelines reflect a model from chemistry that might be relevant to promoting governance and security in the life sciences.

The BWC’s Convening Capacity: Fostering Action on Codes

In 2005 the topic for the Meeting of Experts (MX) of the BWC was the “content, promulgation and adoption of codes of conduct for scientists” (BWC, 2005). A number of national and international scientific organizations were invited to make presentations as “guests of the chair” and there were numerous side events and opportunities for informal discussions during the meeting. As a direct result of their participation in the MX, the leaders of two international scientific unions created codes of conduct that explicitly addressed biological weapons. In addition, the IAP created a Biosecurity Working Group in 2004 specifically to take advantage of the opportunity offered by the meeting and released its *Statement on Biosecurity* at the BWC (IAP, 2005). And, as a result of the statement, the Dutch government asked the Royal Netherlands Academy of Arts and Sciences (KNAW) to create a biosecurity code (KNAW, 2008).

In 2014, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Italy, Mexico, and Spain submitted a *Code of Conduct for Scientists* as a draft document meant to be a code “of general application” for life scientists (Chile et al., 2014). The code discusses professional integrity, personal responsibility (including the improper use of information), and the responsibility of scientific institutions.

In December 2015, the government of China introduced a proposal to develop a code of conduct for scientists under the auspices of the BWC (China, 2015). By the time of the Eighth Review Conference in 2016, Pakistan had joined as a co-sponsor and the draft of a model code had been developed by scholars at the Center for Biosafety Research and Strategy at Tianjin University (China and Pakistan, 2016). Codes of conduct were included in the topics for the 2018–2020 intersessional discussions of developments in science and technology, and, as part of the preparations for the first Meeting of Experts, the BWC Implementation Support

Unit and the Tianjin Center co-hosted an international workshop in June 2018.²²

Examples of Codes from International Scientific Organizations

The development and implementation of a code has been used as one critical strategy for governance. Codes of ethics relevant to biosecurity developed by international organizations include those from the International Union of Biochemistry and Molecular Biology (IUBMB) and the International Union of Microbiological Societies (IUMS), both of which were motivated by the BWC's attention to this issue in 2005:

- *IUBMB Code of Ethics.* The code lists the members' obligation to the public, to other investigators, and to trainees, and also includes that statement 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."²³
- *IUMS Code of Ethics.* "IUMS is opposed to the misuse of microbiological knowledge, research and resources. In particular, IUMS also strives to promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons and therefore to protect the public's health and to promote world peace."²⁴ Member societies are also encouraged to adopt codes.

Examples of Codes from National Scientific Organizations

A number of national academies of sciences and scientific professional societies have also developed and adopted codes:

- *American Society for Microbiology (ASM) Code of Ethics.* The code lists aspirational guiding principles as well as "rules of conduct," which are more specific. Guiding principle 6 states that "ASM members

²² Reports about the workshop may be found in the plenary presentations and a side event hosted by the government of China during the BWC Meeting of Experts in August 2018 (see [https://www.unog.ch/unog/website/disarmament.nsf/\(httpPages\)/6FF7D93E1F743543C125827C0028667D?OpenDocument](https://www.unog.ch/unog/website/disarmament.nsf/(httpPages)/6FF7D93E1F743543C125827C0028667D?OpenDocument) for the plenary presentations and [https://www.unog.ch/80256EE600585943/\(httpPages\)/A8850DE2E9D56A20C125825C003B0E88?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/A8850DE2E9D56A20C125825C003B0E88?OpenDocument) for the side event) (accessed October 5, 2018).

²³ See IUBMB, "Code of Ethics." Available at <https://iubmb.org/about-iubmb/mission-code-of-ethics> (accessed September 21, 2018).

²⁴ See IUMS, "Code of Ethics." Available at <https://www.iums.org/index.php/code-of-ethics> (accessed September 21, 2018).

are obligated to discourage any use of microbiology contrary to the welfare of humankind, including the use of microbes as biological weapons. Bioterrorism violates the fundamental principles upon which the Society was founded and is abhorrent to the ASM and its members. ASM members will call to the attention of the public or the appropriate authorities misuses of microbiology or of information derived from microbiology.”²⁵

- *Indonesian Academy of Sciences Code of Conduct on Biosecurity*. The code was created by the Indonesian Academy of Sciences, with support from the Royal Netherlands Academy of Arts and Sciences and the U.S. National Academies. Introduced in 2015 at the Academy’s 25th anniversary, the code has been disseminated widely within the Indonesian research community (Indonesia, Malaysia, the Netherlands, and the United States, 2015).
- *KNAW Code of Conduct for Biosecurity*. Developed at the request of the Dutch government after the 2005 BWC discussion of codes, the code was released in 2008 and included a dissemination campaign with the research community. Section 4.3 on “dual use” uses a definition similar to that proposed by the U.S. National Science Advisory Board on Biosecurity. The code was reviewed in the wake of the gain-of-function controversy, but revisions were not considered necessary in light of the creation of an extensive outreach program by the Dutch government (KNAW, 2008).
- *Swiss Academies of Arts and Sciences document on “Misuse potential and biosecurity in life sciences research: A discussion basis for scientists on how to address the dual use dilemma of biological research.”* In 2017 the Swiss Academies released a discussion document based on the outcomes of three workshops with life scientists to explore the potential for creating a code of conduct for Swiss researchers. Rather than a code, the consultations resulted in the establishment of six principles that should be considered when doing science, including awareness and assessing misuse potential (Swiss Academies of Arts and Sciences, 2017).

Examples of National Codes, Including Government–Science Community Partnerships

In other cases, codes of ethics and codes of conduct applicable to the governance and oversight of dual use research have been developed by national governments, sometimes in partnership with agencies or

²⁵ See ASM, “Code of Ethics.” Available at <https://www.asm.org/index.php/governance/code-of-ethics> (accessed September 21, 2018).

representatives of national scientific communities. Examples include the following:

- *Code of Professional Ethics for Science Workers in Cuba*. The code lays out ethical principles and rules (both aspirational and advisory). Annex II focuses on biosecurity issues and includes principles similar to those in the IAP Statement, including that scientists must “always bear in mind the potential repercussions—possibly damaging—of their research and recognize that a clear individual conscience does not justify ignoring the possible misuse of their scientific endeavors.”²⁶
- *Science Council of Japan Code of Conduct for Scientists* (revised in 2013 to include dual use). With regard to ethics related to dual use, the revised code states that “Scientists shall recognize that there exist possibilities that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results” (Science Council of Japan, 2013).
- *Malaysian Code of Conduct*. Developed by STRIDE, an institute of the Ministry of Defense, in collaboration with the Ministry of Health, the draft code incorporates feedback and guidance of academic and industry scientists, including the Academy of Sciences Malaysia, collected from workshops held throughout Malaysia in 2015.²⁷
- *Robert Koch Institute and other German Institutions*. As noted earlier in the chapter, the Robert Koch Institute has a code addressing dual use research to which its scientists must adhere. Other German institutions make use of codes to help manage and mitigate dual use as well, including the Technische Universität Darmstadt, Philipps-Universität Marburg, and Fraunhofer Gesellschaft (RKI, 2013).

ENGAGEMENT: AWARENESS RAISING AND OUTREACH

Systematic outreach by governments to inform the relevant communities of their responsibilities and seek their active engagement in imple-

²⁶ See Code of Professional Ethics for Science Workers in Cuba. No official translation. Available at <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G16/221/05/pdf/G1622105.pdf> (accessed September 21, 2018).

²⁷ See ISSUU, “Code of Conduct for Biosecurity, Workshop Handbook.” Available at https://issuu.com/asmpub/docs/code_of_conduct_for_biosecurity_wor (accessed September 23, 2018).

mentation was discussed earlier in the chapter. The issue of engagement was raised by participants over the course of the workshop, with participants suggesting that engagement allowed norms and ideas to be planted and adapted as science changes. Awareness-raising efforts support and supplement other governance activities related to dual use and are often undertaken by professional societies and nongovernmental organizations. Whether included in regularly scheduled events such as annual conferences or held as special meetings, hundreds of such activities take place each year. The workshop discussions suggest that, unfortunately, relatively few organizations have the resources to carry out such activities in a sustained and strategic manner and there is no systematic evidence of their effectiveness. Nonetheless, they constitute a continuing global effort to bring the issues to the attention of the scientific community:

- *Croatian Society for Biosafety and Biosecurity*. As an example of civil society engagement in awareness raising, the Croatian Society conducts training and education programs, organizes conferences, and works on the development of strategy and laws. Future activities are expected to include more attention to dual use issues.
- *Moroccan Biological Safety Association*. The Moroccan Biosafety Caravan was developed through the Moroccan Biological Safety Association with the objective of raising awareness on biosafety and biosecurity in public and in private universities throughout the country. The caravan approach is composed of a traveling series of conferences led by Moroccan biosafety professionals. The outreach is supported with presentations and materials on biosafety, its challenges, and its strategic importance for Morocco.²⁸

EDUCATION EFFORTS AND DEVELOPMENT OF MATERIALS²⁹

Many participants raised the topic of education and training, with education of scientists as a foundational element for the governance of dual use research. This includes modules and courses, as well as materials that can be used to teach and engage with scientists about dual use issues. Activities that introduce dual use issues and biosecurity within a wider context, such as the responsible conduct of science, can serve as the basis for more advanced and specialized training.

²⁸ Further information is available at <https://www.slideshare.net/UNESCOVENICE/caravane-bio-mohammed-benbouida-ambs-morocco-12664659> (accessed October 7, 2018).

²⁹ An extensive discussion of these issues, many of which remained relevant to the Zagreb workshop participants, may be found in NRC (2011b).

Education Programs

Education was seen by a number of participants in the workshop as an ongoing activity, not something that happens once and for which researchers will never need additional engagement as science advances. This includes building networks of faculty who can support each other, share best practices, and sustain capacity-building efforts.

- *European Union CBRN Centres of Excellence Projects Project 18.* The “International Network of universities and institutes for raising awareness on dual-use concerns in bio-technology” was a 2-year activity (2013–2015) “To raise awareness of dual-use (peaceful use and misuse) concerns in bio-technology for academics, scientists, researchers, technicians and students, as well as to foster the sharing and transfer of best practices in biosafety and biosecurity.”³⁰ Information about the implementation of the project is available on the website of the implementer, the Landau Network Centro Volta. A similar project (#42) was carried out for chemistry. This example reflects a multilateral (EU) government activity in support of awareness raising.
- *International Educational Institutes on Conducting Responsible Science, United States.* The U.S. National Academies has carried out a program in cooperation with a number of global partners focused on responsible science. Collegiate-level researchers and educators took part in a program for up to 18 months, first attending a 5-day-long Educational Institute on Responsible Science. The “immersive learning experience [is] constructed to educate on three core themes: the development of professionalism in science, conducting research responsibly, and being part of the responsible scientific community.”³¹ Dual use issues are treated as a component of responsible conduct of research. The Educational Institute used a diverse collection of active learning and assessment techniques—diverse both in the goals and methods used and in the audiences

³⁰ See CBRN Centres of Excellence, “Project 18: International Network of universities and institutes for raising awareness on dual-use concerns in bio-technology.” Available at <http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/46/Project-18-International-Network-of-universities-and-institutes-for-raising-awareness-on-dual-use-concerns-in-bio-technology.aspx> (accessed October 4, 2018). And “Project 42: Chemical safety and security in Central and Eastern Africa.” Available at <http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/78/Project-42-Chemical-safety-and-security-in-Central-and-Eastern-Africa.aspx> (accessed October 4, 2018).

³¹ See National Academies of Sciences, Engineering, and Medicine, “About the Institutes.” Available at <http://nas-sites.org/responsiblescience/iircs/about-the-institutes> (accessed October 4, 2018).

the project strives to reach—to engage the attendees in learning. Following the Institute, attendees were able to competitively apply for modest funds to help them implement teachings of responsible science in their home institutions. A reunion meeting at the end of the program brought together the grantees to provide assessment and feedback and discuss with the program faculty and staff their experience from implementing activities in their home institutions. Six 18-month-long Educational Institutes have been held to date: three regional Institutes in the Middle East and North Africa; one in South and Southeast Asia (MENA); a combined program in Egypt composed of two institutes (two opportunities for funds and one combined reunion was led by Egyptian alumni of previous regional MENA activities); and a shorter 4-day institute in India. Numerous workshops have originated from these activities, delivering aspects of active learning and the message of responsible science, including dual use issues, in a more compressed manner.

- *Centre for Biosecurity and Biopreparedness (CBB), Denmark.* Among its activities, the CBB has a large number of outreach and educational activities where dual use technology is addressed specifically. Teaching and awareness-raising activities are arranged for biosecurity officers, university life sciences students at all levels, and researchers. There is also a Code of Biosecurity Ethics.
- *Dual Use Education in Pakistan.* “Previously, the results of the survey on ‘Awareness and Opinions on Biosecurity and Dual Use among Pakistani Life Sciences Students’ revealed that overall awareness level about dual-use related concepts was low among a sample of students surveyed from Pakistani universities” (Shinwari, 2015: 38). Subsequently, several workshops have been conducted in Pakistan by the Pakistan Academy of Sciences and Quaid-i-Azam University for teaching “responsible science conduct” to the scientists, with young researchers as the main target audience. In order to make the program of scientific training more effective, participatory and interactive learning has been encouraged during the workshops. This approach has proved effective in promoting education on dual use issues in the context of Pakistan (Shinwari, 2015).
- Workshop participants described a number of additional education and training programs that have been undertaken around the globe, including in Algeria, which has developed a training program that looks at dual use issues for scientists; in China, which offers an elective course on dual use to students; through the Japanese National Defence Medical College, which has established a dual use biosecurity education program; in Switzerland, which

has developed a course on the dual use dilemma using online resources; and in Thailand, where educational workshops have been held.

Educational Materials and Resources

Coupled to the increasing number of workshops, courses, and educational opportunities are an increasing number of available resources for scientists wishing to learn about dual use and biosecurity concerns, or to teach them to their students.

- *Malaysian Educational Module on Responsible Conduct of Research from the Academy of Sciences Malaysia*. The module, which is described in the presentation by Abhi Veerakumarasivam (see Chapter 2), includes dual use as one of the elements that make up responsible conduct of research. The chapter on dual use includes reading materials, discussion questions, and suggestions for various active learning activities.
- *Materials Developed by the Bradford Disarmament Research Centre, United Kingdom*.³² Over the years, the group at Bradford has produced a series of online educational resources:
 - The Dual-Use Bioethics Education Module Resource (EMR), which is a joint project among the Bradford Centre, the National Defence Medical College of Japan, and the Landau Network Centro Volta in Italy, provides an online collection of 21 lectures with notes, references, and videos. It covers BWC history and background, dual use issues, and governance issues.
 - The National Series (NS) resource collection provides teaching guidelines and materials for facilitators, whether or not they are biosecurity subject matter experts, that can be adapted for different countries beyond the countries for which specific materials are available.
 - *Preventing Biological Threats: What You Can Do* is an edited volume 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 companion handbook, *Biological Security Education Handbook: The Power of Team-Based Learning*, provides a number of the exer-

³² Materials are available at <https://www.brad.ac.uk/bioethics> (accessed November 12, 2018).

cises related to dual use issues and/or the responsibilities of scientists.

In addition to this work, the Bradford Centre has produced material focused on dual use issues related to neuroscience.

- *Case Studies in Dual Use Biological Research and Case Studies in Agricultural Biosecurity from the Federation of American Scientists.* The Federation of American Scientists in the United States developed dual use case studies intended to help define the issues associated with dual use research and security in the research laboratory. They include interviews with researchers whose legitimate scientific work could potentially be used for questionable or harmful endeavors, as well as a historical perspective on their research, bioterrorism, and research regulations. The materials include primary scientific research papers and discussion questions that are meant to raise awareness about the importance of responsible biological research. The agricultural biosecurity modules are intended to raise awareness about agricultural biosecurity issues in the United States and are targeted toward the educated public. These modules address two different aspects of agricultural biosecurity: the nexus of agricultural production and international security. They include interviews with experts, historical perspectives on agroterrorism, and regulations.

Networks and Clearinghouses

Throughout the workshop, a number of participants noted the importance of creating and sustaining networks of people interested in education on dual use life sciences research, as well as repositories of relevant materials that can be used by those wishing to implement educational activities.

- *International Network on Biotechnology (INB), UNICRI.* The INB is a global network of academic and research institutions, nongovernmental and international organizations, and other stakeholders in Asia, Europe, the MENA, and North and South America committed to advancing responsible and secure conduct in the life sciences. Its primary goals are to
 - Raise awareness about the opportunities and risks enabled by advances in biotechnology,
 - Advance responsible life sciences education,

- Advocate practical (policy) measures to ensure sustainable progress in biotechnology, and
- Enable partners to fulfil their international obligations.³³

In its clearinghouse role, the INB is developing a digital platform to view, download, upload, and share customizable and user-friendly teaching and training materials, which include technology briefs, case study videos, scenario-based exercises, and immersive learning (VR laboratory tours). The INB also provides a sustainable platform for Network Partners to (co-)develop and share educational resources tailored to local needs.

COORDINATION AND CONSENSUS BUILDING

A recurring theme in the Zagreb workshop reflected in the meeting's title—Advancing Global Consensus on Research Oversight—was the potential need to develop greater common understandings about effective means and measures for the oversight of research with dual use potential that could support both security and continuing, globally accessible scientific progress. The second background document provided to participants contained a list of current and potential international forums and initiatives where such understandings could be built, promoted, and, where appropriate, implemented at the international, regional, or national level. Some of the forums have security as their primary mission, but others engage key stakeholders or address issues that can support more effective governance of research with dual use potential. None are devoted to dual use issues.

Some of the intergovernmental forums, based on formal treaties, have the capacity to make decisions that impose legally binding obligations on member states. Some serve as policy coordination bodies, and these may lead to increased harmonization of national policies and actions. Other intergovernmental forums primarily provide an opportunity for discussion among member states—and sometimes relevant stakeholders—about key issues. And to add to the complexity, there are also initiatives that seek to coordinate and enhance the work of the intergovernmental bodies themselves in areas where there are common interests.

Moreover, there are many international nongovernmental organizations that also provide valuable forums that have the capacity to build common understandings. The background document concentrates on those related to the workings of the scientific community. These bodies

³³ See INB. Available at [https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/DB56FEF7FA3325E82C12582E4006A837A/\\$file/INB_Presentation_BWC+MXaug2018_9+Aug+2018.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/DB56FEF7FA3325E82C12582E4006A837A/$file/INB_Presentation_BWC+MXaug2018_9+Aug+2018.pdf) (accessed October 4, 2018).

TABLE 3-3 Selected Examples of International Forums

Types	Examples
Disarmament Conventions and Forums	<ul style="list-style-type: none"> - Biological Weapons Convention - United Nations Security Council Resolution 1540 Committee
Other Intergovernmental Organizations	<ul style="list-style-type: none"> - World Health Organization - World Organisation for Animal Health (OIE)
Security Policy Coordination and Action Forums	<ul style="list-style-type: none"> - Australia Group - European Biosecurity Regulators Forum - International Experts Group of Biosafety and Biosecurity Regulators - Global Health Security Agenda - Global Partnership Against the Spread of Weapons and Materials of Mass Destruction
International Science Forums	<ul style="list-style-type: none"> - World Science Forum - World Conferences on Research Integrity

focus largely on traditional research integrity issues in the context of the rapid globalization of science, but they could in principle include security. And there are scientific communities of practice that provide examples of the ways that the scientific community can self-organize.

The workshop did not attempt a comprehensive review of the potential international venues. The remainder of this section offers a few of the examples that were discussed in an effort to give a sense of the variety and potential for seeking greater international consensus (see Table 3-3).

Disarmament Conventions and Forums

The two examples most frequently cited during the workshop were the BWC and the UN1540 Committee, both of which have been described earlier. Most relevant here are the example of the BWC's convening capacity in relation to promoting codes of conduct as a governance tool and the adoption of UNSCR 2325 in 2016, which explicitly encourages states to address intangible technology and information.

Other Intergovernmental Organizations

Intergovernmental organizations that address issues that are relevant to the governance of dual use research include the World Health Organization (WHO), the World Organisation for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), and the

Convention on Biological Diversity and its Nagoya Protocol. Some of the work of UNICRI, another example, was described above. WHO, OIE, and FAO are partners in the Global Health Security Agenda described below. In addition:

- *World Organisation for Animal Health (OIE)*. As the *Biological Threat Reduction Strategy* released by OIE in 2015 notes: “At least 75% of emerging infectious diseases of humans (including Ebola, HIV, and influenza) have an animal origin” and “80% of agents with potential bioterrorist use are zoonotic pathogens” (OIE, 2015a: 2). This provides the organization with a strong rationale and role in international efforts to reduce biological risks, whether natural, accidental, or deliberate, particularly as a partner in a “one health” approach to combating infectious disease. The clearest link in the strategy to dual use issues is the goal to “Advocate that fostering of altruistic scientific networks at the national, regional, and global level is a means of sustaining expertise, and preventing scientists from contributing to bioweapons development by encouraging a culture of responsible and transparent science” (OIE, 2015a: 7). OIE is a regular participant in the work of other intergovernmental organizations and has held two international conferences on biosecurity of its own, one in 2015 and one in 2017, both of which included discussions of dual use issues.³⁴
- WHO has become involved in dual use issues over the past 15 years, although they have never been a consistent focus for the organization. For example, the organization released a paper in 2005, *Life Science Research: Opportunities and Risks for Public Health* (WHO, 2005), and held a workshop in 2006 on “Life Science Research and Global Health Security” (WHO, 2007). Several regional workshops during the same period addressed both biosafety and biosecurity issues, and a guidance document released in 2010 offered researchers and laboratories a self-assessment tool to evaluate their oversight of dual use research (WHO, 2010). Most recently, WHO, which has a key role in research and policy related to influenza, was an active participant in the international debate over gain-of-function research.

³⁴ The proceedings of the first event have been published (OIE, 2015b) and information about the second may be found at <http://www.oie.int/eng/BIOTHREAT2017/introduction.htm> (accessed October 4, 2018).

Security Policy Coordination and Action Forums

Over the years, a number of bodies have been created to enable governments to discuss, formulate, and sometimes implement action in specific areas such as export controls. The focus is often on technical issues and is intended to support coordinated and consistent policy. The narrower membership sometimes makes the bodies subject to criticism and they do not normally include key stakeholders in their deliberations. But forums of this type may be most able to achieve “harmonization” across at least some policy areas.

- *The Australia Group (AG)*. Created in 1985, the AG seeks to improve consultation on export controls among its “participants.” Its original focus on chemical weapons was expanded to biological weapons in the 1990s. Forty-two countries now participate in the AG—India joined in January 2018—and the European Union takes part as an institution. According to its website, “[T]hrough the harmonization of export controls, [the AG] seeks to ensure that exports do not contribute to the development of chemical or biological weapons.”³⁵ Common control lists for “dual use biological equipment and related technology and software, biological agents, and plant and animal pathogens” serve to promote common standards and regulations. The AG also provides a forum for discussion of dual use issues, including dissemination of information. For example, when the Netherlands chose to rely on export controls as the policy mechanism for its response to the experiments in a Dutch laboratory that provoked the gain-of-function controversy, the AG discussed the issues.
- *European Biosecurity Regulators Forum (EBRF)*. Initiated in 2013 in the context of the EU CBRN Action Plan, the group began with a focus on “ways of securing biological substances with dual-use potential”³⁶ and produced a guideline with best practices and examples of national implementation of biosecurity. In 2014, the group continued cooperation with an expanded focus toward awareness-raising activities of biosecurity and dual use issues. Since an inaugural meeting in 2015, representatives of national regulatory bodies of the seven current EBRF members (Denmark, France, Germany, the Netherlands, Sweden, Switzerland, and the United Kingdom) have continued to meet to discuss important biosecurity and dual use topics. In 2016, the EBRF produced a

³⁵ See The Australia Group. Available at <http://www.australiagroup.net/en/index.html> (accessed October 4, 2018).

³⁶ See EBRF. Available at <http://www.ebrf.eu/about.html> (accessed October 4, 2018).

working paper on securing “immaterial technology” as a particularly important dual use issue (EBRF, 2016).

- *The International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)*. IEGBBR is an ad hoc group of representatives from national regulatory programs in biosafety and biosecurity. The group, which meets biennially to discuss issues in the regulation of biological pathogens, is not an official organ of the United Nations or any national government. The first meeting was held in Canada in February 2007 with participants including experts from Australia, Brazil, Canada, Denmark, France, Germany, Japan, the Netherlands, Singapore, Switzerland, the United Kingdom, and the United States. The IEGBBR cites five major goals: “to act as the focus point for the development of an international network of advisors in matters related to the regulation of human pathogen biosafety and biosecurity; to benefit members through active discussion of current and emerging issues relating to human pathogen biosafety and biosecurity and to share best practices and lessons learned; to benefit members through discussion and sharing of related programs, expertise, and approaches; to encourage coordination among national regulators in order to ensure greater compatibility and interoperability of biosecurity and biosafety systems and processes; and to promote the development of effective biosafety and biosecurity regulation internationally including the building of capacity in fields such as inspections, risk assessment, safety measures, [and] oversight mechanisms” (Weyant, 2013).

Complex global issues increasingly cut across the interests and jurisdictions of traditional intergovernmental organizations. In response, rather than create new bodies to tackle the problems, less formal “networks of networks” provide a way to develop and coordinate initiatives. The Tripartite Collaboration established by WHO, OIE, and FAO to provide a coordinated approach to reducing the threat of increasing antimicrobial resistance is an example of the type of activity that could be developed to enhance oversight of dual use research.³⁷ The Global Health Security Agenda (GHSA) is an example of a complex international initiative that, although primarily focused on traditional biosafety and laboratory biosecurity issues, acknowledges dual use risks and may address research oversight in cases where it is relevant.

³⁷ See WHO, “Food Safety.” Available at http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/tripartite/en (accessed October 4, 2018).

- *Global Health Security Agenda (GHSA)*. Launched in early 2014, the GHSA is a partnership among intergovernmental organizations, individual countries, and nongovernmental stakeholders with a mission to “strengthen both the global capacity and nations’ capacity to prevent, detect, and respond to human and animal infectious diseases threats whether naturally occurring or accidentally or deliberately spread.”³⁸ The GHSA now has more than 60 member countries, and the three original intergovernmental partners—WHO, OIE, and FAO—have now grown to include Interpol, the UN Office for Disaster Risk Reduction, and two regional bodies, the European Union and the Economic Community of West African States. One way that GHSA member states participate is through their commitment to specific Action Packages that support the three overarching themes of “Prevent, Detect, and Respond.” Each package includes 5-year targets and performance indicators. Of the 11 Action Packages, “Prevent 3: Biosafety and Biosecurity” is the only one that addresses issues relevant to the workshop, with the following 5-year target:

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.³⁹

- *Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (Global Partnership or GP)*. The GP is “an international initiative aimed at preventing the proliferation of chemical, biological, radiological and nuclear weapons and related materials.”⁴⁰ It was launched at the summit of the then G8 countries in 2002, with a focus on preventing terrorists from acquiring weapons of mass destruction. Thirty countries and the European Union are

³⁸ See <https://www.ghsagenda.org> (accessed October 4, 2018).

³⁹ See GHSA, “Biosafety and Biosecurity Action Package.” Available at <https://www.ghsagenda.org/packages/p3-biosafety-biosecurity> (accessed October 4, 2018).

⁴⁰ See GP, “About the Global Partnership.” Available at <http://www.gpwmd.com/about> (accessed October 4, 2018).

now active members and, among other activities, participate in GP Working Group meetings twice per year, including one devoted to biological threats. Of the five deliverables that form the Biological Threats Working Group strategy and underpin its collective programming, two are directly relevant to oversight of dual use research: “Reinforce and strengthen biological non-proliferation principles, practices and instruments” and especially “Reduce proliferation risks through the advancement and promotion of safe and responsible conduct in the biological sciences.”⁴¹

International Science Forums

The discussion earlier in this chapter of norms and codes of conduct as ethical foundations for governance of research with dual use potential introduced a number of international scientific organizations. In addition, there are additional venues where biosecurity governance issues could be addressed as part of efforts to engage the government officials who make science policy and fund research. Two other examples are provided below. To date, these organizations have not shown a systematic interest in dual use or security issues, so trying to engage them could be a significant new effort. The potential reward would be the addition of authoritative voices from the scientific community that are already deeply engaged in responsible conduct of science to the promotion of dual use governance.

- The oldest activity is the biennial World Science Forum (WSF), which began as a collaboration among the Hungarian Academy of Sciences, UNESCO, and the International Science Council in the late 1990s. In 2011, the decision was made to expand the WSF beyond its traditional home in Hungary, and now the biennial event alternates between Budapest and a venue outside Europe. The consensus statements produced at the end of each Forum provide an additional foundation for the social responsibility of science but do not address security issues. The theme of the 2019 WSF, to be held in Budapest, will be “The Ethics and Responsibility of Science.”
- The World Conferences on Research Integrity (WCRI) began in Lisbon in 2007. The organization aims to give “researchers, teachers, funding agencies, government officials, journal editors, senior administrators, and research students opportunities to share expe-

⁴¹ See GP, “Biological Security.” Available at <http://www.gpwmd.com/bswg> (accessed October 4, 2018).

riences and to discuss and promote integrity in research.”⁴² The first five conferences were organized on an ad hoc basis but, as of 2017, the World Conferences have been established as a nonprofit organization with headquarters in the Netherlands. The sixth conference is to be held in Hong Kong in 2019 with the theme of “New Challenges for Research Integrity,” with a discussion planned about “the importance of *embedding education* on responsible conduct of research into institutions and evidence on how this can be delivered in the most effective way.”⁴³ Three of the conferences have produced consensus statements (“Guidance”); the statement produced by the second conference in Singapore included “Societal Considerations: Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work” (Second World Conference on Research Integrity, 2010).

SUMMING UP

This chapter has provided an overview of the discussions that took place during the workshop’s breakout sessions. The bulk of the chapter focused on providing examples of current governance activities along the various stages of the research life cycle, as well as efforts in awareness raising and education that provide the foundation for implementation. The examples illustrate the range and variety of initiatives from governments and the scientific community to create and support governance of dual use research. The chapter also describes a number of international forums that provide the opportunity to develop—and in some cases implement—common understandings about specific approaches to governance, as well as norms of scientific responsibility that support effective implementation. The next chapter presents a review of the ideas and issues, arranged thematically, that emerged from the discussions.

⁴² See WCRI, “6th World Conference on Research Integrity.” Available at <http://wcri2019.org> (accessed October 4, 2018).

⁴³ See WCRI, “6th World Conference on Research Integrity.” Available at <http://wcri2019.org> (accessed October 4, 2018).

Workshop Discussions

INTRODUCTION

During breakout sessions, in reports back from session rapporteurs, and in plenary discussions, participants raised a number of points about current approaches to the oversight for dual use life sciences research, gaps and challenges that remain, and suggestions for further actions that might continue to strengthen research oversight systems and promote greater common understanding internationally. These discussions are described thematically below.

STRENGTHENING THE CURRENT GOVERNANCE LANDSCAPE

The Importance of National and Institutional Spaces for Dual Use Discussions

Countries use varied approaches to address concerns about dual use of life sciences research. For example, a participant suggested that the U.S. Dual Use Research of Concern (DURC) policy described in Chapter 3 has resulted in researchers and research institutions paying more serious attention to the issue of dual use than they would have in the absence of such a policy, along with qualitative indications of increasing awareness among the scientific community. Similarly, it was noted that a national policy has increased awareness among the multiple U.S. agencies involved in life sciences research, since all are required to keep track of work with the 15 agents and 7 experiments captured by the policy.

Another participant noted that there is evidence that scientists and U.S. research-conducting institutions are using the list-based DURC policy as a starting point while going beyond the specific requirements, for example, to screen a wider portfolio of research for potential dual use. Because there is now an institutional focal point to serve as a resource, the participant noted that investigators can come voluntarily to discuss whether anticipated research would raise dual use concerns. These were all seen as positive developments. On the other hand, participants noted U.S. DURC policy is limited to certain pathogens and not all institutions work with such agents. This means not all universities or other research-performing institutions would have a relevant institutional review entity and implementation remains limited in scope.

Building on this discussion, many participants noted the value of national and institutional “homes” for discussions of dual use. At the national level, this may be a ministry, an advisory body or council focused on biosecurity, biosafety, or bioethics, or some other option. For example, France has a National Advisory Council for Biosecurity that is empowered to make recommendations for the funding, conduct, and dissemination of dual use research; Singapore has established a national Bioethics Advisory Committee;¹ and Malaysia has developed a National Biosafety Board. A participant suggested that the online presence of such bodies can also act as a centralizing focus of activity and can help identify and circulate information on measures such as codes or oversight mechanisms at the national level. In addition, a national body such as a dual use research advisory committee could play a role in reviewing selected proposals and providing advice to relevant government agencies on risk assessment and risk mitigation plans. Such a role could be akin to the U.S. Recombinant DNA Advisory Committee, which is asked to review certain protocols and provide recommendations to the National Institutes of Health (NIH) “related to basic and clinical research involving recombinant or synthetic nucleic acid molecules.”² Many workshop participants similarly saw having a home for dual use life sciences discussions within research institutions as a significant component of the oversight system. Models are

¹ Background materials are available at Bioethics Advisory Committee Singapore. Available at <http://www.bioethics-singapore.org/index/publications/reports/172-research-involving-human-subjects-guidelines-for-irbs.html> (accessed September 4, 2018).

² See NIH, “Recombinant DNA Advisory Committee.” Available at <https://osp.od.nih.gov/biotechnology/recombinant-dna-advisory-committee> (accessed September 4, 2018). At the time of publication, NIH had undertaken a process of formal public consultation about a proposal “to streamline oversight for human gene transfer clinical research protocols (i.e., gene therapy research) and reduce duplicative reporting requirements already captured within the existing regulatory framework” (<https://osp.od.nih.gov/biotechnology/nih-guidelines>; accessed October 2, 2018).

likely to vary but this responsibility currently appears to be carried out primarily through some type of institutional review committee.

The Importance of Context

It was widely acknowledged among participants that the context in which governance measures are applied is important, with differences in systems of government, culture, language, resources, and priorities requiring consideration in the development of governance measures. In many cases, they saw an important role for both government actions and self-governance activities by the scientific community. The balance between these approaches and how it is achieved is likely to vary. As an example, various participants pointed out that some countries take a more top-down legislative approach to addressing dual use issues, while others take a more bottom-up approach led by scientists. Certain countries view biosecurity and biosafety as components to be tackled together or feel that biosecurity can only be successfully addressed in the context of a strong, existing foundation in biosafety, while others see these as separate issues to be tackled discretely. There was, as such, no “one-size-fits-all” approach to dual use governance of life sciences research and specific measures need to be adapted to suit the context.

Common Elements of the Layered Governance System

Despite variety in the details of how governance of dual use life sciences may be implemented in diverse contexts, some participants suggested components of research oversight systems that might provide useful common elements (see Table 4-1). These components are not intended to be comprehensive or to serve as consensus recommendations; rather, they provide inputs for further stakeholder discussions. The details of how such components would be designed and function in particular countries or research communities will vary with context, but building common understandings about these elements can further strengthen dual use governance.

Mapping Progress

Throughout the workshop discussions, it became clear that a considerable number of governance activities have been undertaken over the past decade or so. Efforts to develop and promote codes of conduct, education, and awareness, for example, have resulted in concrete initiatives around the globe, including in China, Germany, India, Indonesia, Japan, Malaysia, Morocco, the Netherlands, Pakistan, Switzerland, the United

TABLE 4-1 Elements That Could Contribute to an Oversight System for Dual Use Life Sciences Research

Stage	Oversight Element
General	<p>Having a “home” where discussions on governance of dual use research can occur, both nationally (such as a biosafety or biosecurity advisory body) and institutionally (such as through a review committee).</p> <p>Proactive outreach by government regulators to researchers to inform them of their obligations and provide a mechanism for consultation as needed.</p> <p>Efforts that promulgate awareness raising, norms of responsible conduct, and training on risk management for life sciences researchers.</p> <p>Engagement with the private sector, which remains a relative gap among the activities discussed during the workshop.</p>
Research Conception and Funding	Processes for considering the potential dual use risks and benefits associated with research proposals, coupled with the development of risk management plans.
Conduct of Research	<p>Oversight systems at research-conducting institutions, including oversight processes for research projects beyond a set of specified agents and experiments (e.g., options for addressing governance of experiments that do not fall within the particular limits of “DURC” as defined by U.S. policy).</p> <p>Development and adoption of practices to prevent misuse of research materials and resources. For example, encouraging ongoing advances in nucleic acid screening and the universalization of screening best practices from organizations such as the International Gene Synthesis Consortium (IGSC).</p> <p>Establishment of relevant norms and guidelines of practice by life sciences research communities (for example, analogous to the widely respected guidelines for stem cell research developed by the International Society for Stem Cell Research).</p>
Dissemination and Publication	<p>Practices, frameworks, or capacity-building resources to enable prepublication archives, journal editors, and publishers to review submissions for dual use concerns.</p> <p>Legislative and regulatory measures to manage dissemination.</p>

Kingdom, and the United States, among other countries. Chapter 3 and the background materials in Appendix E provide a number of examples of activities that have been undertaken. The list is not comprehensive; it reflects what workshop organizers gathered in advance of the meeting and additions shared by workshop participants.

Several participants argued that, in the short term, it would be useful

to conduct further inventory mapping exercises to determine still more systematically who is doing what in a wider range of countries. Such a process could aid in the development of a library or repository of tools and materials that have been used in national, regional, and international dual use governance initiatives. Such an inventory might further inform interested stakeholders of the tools available as they articulate their requirements.

Terminology

Participants commented on the continuing difficulties posed by confusion or disagreement over terminology. Translation of terms across languages is a major challenge. Perhaps the most familiar issue is that the term “biosecurity” either does not exist or is the same word as “biosafety” in a number of languages, including Chinese, French, German, Russian, and Spanish (NRC, 2011b: 20). Moreover, biosecurity does not always include dual use issues; the term “laboratory biosecurity” is used to describe measures focused on the physical security of agents and toxins, personnel reliability, and access to facilities (OECD, 2007; WHO, 2004). In response, some prefer the term “biorisk management” to encompass both biosafety and biosecurity, which may include dual use, but it has not yet achieved widespread use. And as mentioned in Chapter 1, “dual use” also has a traditional meaning in disarmament and arms control to describe “goods, software and technology that can be used for both civilian and military applications”³ rather than the workshop’s definition as research that, while intended for beneficial purposes, could also be misused to cause deliberate harm. Many participants thought that fostering shared definitions of what is encompassed by key terms will continue to be important in creating the common understanding necessary for effective dual use governance.

Building Common Understandings and Frameworks

In the longer term, the process of mapping governance activities and progress could facilitate sharing of information, lessons learned, and best practices. It could allow stakeholders to build common global understandings and to create templates for governance strategies, policy options, training, and awareness raising that interested parties could adapt, taking into account the local context. As several participants noted,

³ See European Commission, “Dual-use trade controls.” Available at <http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls> (accessed October 2, 2018).

such an effort would require someone to take the initiative, with some participants suggesting that a working group might be established to undertake this task.

One concrete proposal from some participants was the development of a document articulating principles for the governance of dual use research in the life sciences. Such a project would collect and collate the considerable body of work already produced by international, regional, and national scientific organizations. This material could include statements on the responsibility of scientists, materials elaborating ethical principles related to dual use, and other biosecurity-related resources. Illustrative examples such as the InterAcademy Partnership (IAP) Statement on Biosecurity and the document on Scientific Freedom and Scientific Responsibility developed jointly by the German Research Foundation and the German Academy of Sciences Leopoldina were described in Chapter 3. The document could be disseminated as a means of fostering continued dialogue and the building of common understandings.

Several participants also suggested that, while a principles document was being drafted, there could be a parallel process of developing evidence-based strategies for the uptake and implementation of governance measures. While examples of relevant governance principles are already available, they need to be operationalized to enable them to be put into practice, and these participants suggested that this aspect is likely to be a challenge. They also pointed out that implementation of dual use governance principles will require encouraging wider networks and actors to take ownership of the principles and adapt such materials to their local needs and contexts.

Contributions of Social and Behavioral Sciences

The workshop planning committee gave particular attention to the potential contributions that insights from the social and behavioral sciences could make to the design, implementation, and assessment of governance measures. The talks by Ruthanne Huisling and Baruch Fischhoff described in Chapter 2 illustrate the contributions of several interdisciplinary fields, including decision science and organization studies. Other examples emerged during the breakout sessions. Table 4-2 provides a list of some of the challenges for governance identified during the workshop and the areas of social and behavioral sciences that participants cited as particularly relevant to addressing them. In addition, the field of Science and Technology Studies (STS) provides a range of analytic approaches that cut across the governance challenges listed in the table.

TABLE 4-2 Contributions of the Behavioral and Social Sciences to Governance

Governance Challenge	Relevant Research Fields
Identifying and assessing risk	Decision Science
Fostering scientist engagement in security	Science of Science Communication
Promoting and sustaining a “culture of responsibility” in science	Organization Studies
Designing appropriate governance measures and strategies	Anticipatory Governance
Cross-cutting	Science and Technology Studies

GOVERNANCE ACTIVITIES ACROSS THE RESEARCH LIFE CYCLE

A number of workshop participants argued that longer-term progress will require aligning and organizing multiple opportunities and check-points for dual use governance that operate along a continuum of scientific activity beginning at the preaward stage.

Research Conception

Some participants argued that there is a foundational role for awareness among scientists of the potential for their research to raise dual use concerns. In addition, participants cited the governance examples discussed in the workshop as evidence of the important roles played by institutional review and oversight processes, as well as the contribution of further development and application of technical control and mitigation mechanisms. For example, as Kanabrocki’s presentation and other examples illustrated, there is scope for bodies at research-conducting institutions to review proposed research for dual use concerns. Some participants suggested a number of options that could be considered when concerns are identified. Binding recommendations for changes to research protocols, biosafety levels at which research is conducted, or other modifications to the conduct and dissemination of the research could be made as a condition of obtaining institutional approval. Funders may require documentation of institutional approvals addressing other aspects of research oversight (reviews for appropriate protection of human subjects, use of animals, use of recombinant DNA, etc.) prior to issuing an award or at least prior to such research commencing and one could envision similar institutional approvals for dual use research.

In addition to the changes in how research is conducted as described above, participants suggested that other types of technical measures could be considered at the conceptual or planning stage, as well as during the conduct of research. These measures include incorporating mechanisms aimed at improving biological control and mitigating concerns over misuse into the research. As noted by Charo, the Defense Advanced Research Projects Agency is investigating biological control mechanisms through its Safe Genes program. One example raised could be a strategy in which a gene drive is only active in the presence of a secondary substance, a mechanism intended to provide additional ability to regulate when gene editing does and does not occur.

Funding

Participants also discussed how funding agencies, private foundations, and other funders can play valuable roles in dual use governance, particularly through requiring researchers to include an assessment of dual use potential as part of the funding application process. As noted in Chapter 3, there are already examples of funding bodies, such as NIH in the United States and the joint initiative of the Wellcome Trust and the two government research councils for life sciences in the United Kingdom, that obligate applicants to consider dual use potential. Implementation of review measures for potential dual use at the proposal stage is intended to bring awareness and assessment of anticipated risks and benefits early in the research life cycle. On the other hand, participants noted that widespread adoption of dual use review by the funding community will require further discussions on the types or categories of experiments that should be assessed (e.g., a broad request or more narrowly focused set of pathogens and experiments), how to evaluate researcher responses, and methods to scale up checking funding applications for completion of the assessment requirement. Still others cautioned that the requirement to address dual use potential in research proposals could become a box-checking exercise and expressed concern that responsibility for completing these boxes would be delegated from the principal investigator to administrative or research assistants. Successes, challenges, and lessons may be drawn from the experiences of the funders who currently require dual use assessment and further discussions among the funding community on this topic may be useful.

Conduct of Research

Institutional Review Committees⁴

As noted above, a number of participants highlighted the important role of institutional review bodies that assess potential dual use concerns posed by life sciences research and are capable of stipulating and enforcing requirements for the appropriate conduct of research. One participant suggested that the Robert Koch Institute in Germany (see Chapter 3) can serve as a model for how a research institution can implement oversight of dual use research. Having a system that includes a code of conduct, risk assessment criteria, multiple evaluation points over the course of research, and identified institutional procedures for documentation and reporting could prove particularly useful in circumstances where unexpected results emerge in the conduct of research. Israel offers an example of a similar approach. In Israel, the Regulations of Research into Biological Disease Agents Act (2008) requires institutional biosafety and biosecurity committees comprised of scientists, security experts, and safety personnel to supervise certain types of research. Other participants noted that biodefense research laboratories use other approaches that could serve as models. These or other existing models for institutional oversight could be shared on a larger scale or adapted by other research-conducting institutions to suit their requirements.

Similarly, a participant suggested that the practice of peer review could serve as a potentially useful tool to inform practices around institutional review committees. Countries such as Germany, for example, had initiated peer-review exercises that could be adapted to analyze the practices employed by organizations to review experiments of concern. Convening such discussions among stakeholders from research-conducting institutions in a nonjudgmental manner could further facilitate the sharing of lessons learned and effective practices.

DNA Synthesis Screening

A number of research projects make use of nucleic acid sequences as part their activities. The growing capacity to reconstruct a pathogen from pieces of nucleic acid raises dual use concerns. The screening by commercial providers of DNA synthesis orders is thus one of the tools used to support dual use governance. Some participants cited the work

⁴ Different national systems, policies, or organizations may call such bodies by different names. These proceedings generally refer to such bodies as institutional review committees or institutional review bodies, intending to encompass whatever the relevant body would be called.

of the International Gene Synthesis Consortium (IGSC; see Chapter 3) as an example of a successful dual use governance initiative. However, other participants noted that the processes used for DNA synthesis screening and their effectiveness may become a more complex problem in the future as the industry becomes more decentralized and diversified. Moreover, synthesis screening is not universal, with potential gaps and inconsistencies across jurisdictions. Not all commercial providers are members of an organization that has adopted screening guidelines, such as IGSC, and existing screening guidelines would not necessarily capture sequences synthesized “in house” by a laboratory. As such, several participants cited synthesis screening as an important area to continue to discuss and develop as the industry and academic research environments evolve.

Dissemination of Results

Publication Reviews and Their Limits

Several participants raised the issue of prepublication editorial reviews as a tool of dual use governance. Publicly available information shows the number of articles flagged by editorial reviews as posing dual use issues is tiny. Some participants expressed concern that, despite leading scientific editors producing a statement committing to review publications for security sensitive content, such reviews are not sufficiently thorough. Moreover, these flagged articles have eventually been published, sometimes after revisions or accompanying commentaries, such as the articles at the center of the gain-of-function controversy.⁵ Given this, some workshop participants questioned how effective the process of reviewing publications for dual use content had actually been.

Participants raised several challenges to intervening at the publication stage. One is that the number of publications continues to grow. And while some journals employ professional editors, others rely on volunteer and academic editors who may not have the expertise or time to carry out thorough or consistent screening. Initial screening for potential dual use may be able to be accomplished by screening for key words, but this approach may not be sufficient. As a result, the capacity, resources, and knowledge to implement dual use oversight of articles submitted for publication varies. A second challenge is the pressure on researchers to publish their results, which makes the process of intervening at the point of publication significantly harder.

A third challenge raised during discussion is that the point of pub-

⁵ See NASEM (2017f), in particular pages 15–21, for a discussion of a number of such controversies in the United States.

lication is too late, and dissemination needs to be managed throughout the research life cycle. As a participant pointed out, the gain-of-function controversy was triggered, in part, by a conference presentation by one of the authors prior to publication. Other participants cited the growing use of prepublication servers such as bioRxiv that enable materials to be uploaded and made publicly available prior to copy editing and peer review. One participant estimated that the Public Library of Science (PLOS) journals receive around 1,000 papers each week with at least 20 percent of these prepublished online before being formally peer reviewed. Workshop participants did not know whether these papers received any screening for dual use. Several participants stressed the need to continue to engage publishers of scientific research, and particularly to include prepublication services, in conversations about dual use oversight as part of addressing the changing nature of publication in the life sciences. Other participants suggested that it might be useful to encourage scientists undertaking dual use research not to engage in prepublication.

Research Translation

The workshop discussions suggested that the research translation phase could be explored further for the governance of dual use life sciences research. A number of workshop participants identified tools that could be applied in this regard. Some participants highlighted the potential role of intellectual property (IP) as a tool of dual use governance and noted that this is a key point at which private-sector organizations make their research visible, for example, through patent filings. Several participants suggested the need to engage the private sector more systematically in dual use conversations. Moreover, as Alta Charo had noted in her presentation, IP can also act as a significant source of governance through placing conditions on patent licenses and material transfer agreements to control uses and third-party dissemination. Such governance strategies and tools could be an area for further exploration.

Export Controls

Several participants argued that conventional export control approaches were necessary but imperfect for contemporary governance of life sciences research. Established export control regimes, such as the Australia Group, which includes 42 countries and the European Union, have achieved a number of successes. However, the Group plays a limited role for in-country transfers. Furthermore, some countries that are emerging leaders in biotechnology research or are leading technology suppliers in emerging areas such as 3D printing are not members. In addition, a

participant suggested that determining which materials and technologies should be on export control lists is a particular challenge in the life sciences. The difficulty of separating materials and equipment for legitimate beneficial research from ones that could be misused, especially as the life sciences research enterprise is becoming increasingly global, diverse, and decentralized, was recognized at a number of points during the workshop. Such challenges can frustrate scientists, especially in countries that face difficulties and delays in getting access to these items.

Governing the transfer of intangible assets such as knowledge, data, and IP remains particularly difficult as noted by Bowett (see Chapter 2). Some participants also expressed concerns that the multiple regimes covering export controls, material transfer agreements, intellectual property, and resource sharing (such as the Nagoya Protocol on Access and Benefit Sharing of the Convention on Biological Diversity) can have the net effect of making it more difficult to transfer materials and equipment in crisis situations. The Ebola outbreak in West Africa was discussed as a specific example of how the multiple competing imperatives of different regimes made it difficult to transfer samples out of the affected countries. Some participants argued it would be preferable if the use of controls such as export regimes did not stand alone but instead were incorporated as part of a layered governance system.

ENGAGEMENT

The themes of engagement, awareness raising, outreach, and education arose frequently during the workshop. The number of activities undertaken in the areas of engagement and awareness raising has continued to increase. However, many participants indicated that more inclusive engagement will be required to reach a broader range of relevant actors and stimulate governance activities across the research life cycle.

In the short term, it was suggested that participants could take advantage of immediate opportunities such as engaging with professional biosafety societies, disciplinary societies, or international organizations. Circulating the Zagreb meeting proceedings could be useful for reaching out to scientists, organizations, and countries not represented at the workshop or that have not yet undertaken activities related to dual use governance. In the medium term, further engagement could be pursued through follow-on regional or cross-regional conferences or be focused on particular dual use governance topics, such as publishing or funding. In the longer term, a number of participants highlighted the need to build networks of networks and further engage with the private sector, individuals within the scientific community, and the wider public.

Engaging Scientists

Several participants recognized the significant role played by champions from within the scientific community in advancing dual use governance. Further work could be undertaken to engage a wider range of scientists with a view to raising awareness and identifying and supporting champions that could take the lead in dual use governance. As noted above, many scientists are under pressure to publish and generate project funding, and discussions on dual use governance may not be an immediate area of interest. Accordingly, it might be more fruitful to engage on the science first as a means of building bridges between communities.

In this context, one approach raised was the idea of regional science and technology dialogues. Such meetings of regional and international experts from the public and private sectors would focus primarily on the role of science and technology in addressing regional challenges. However, a secondary component of such dialogues would involve discussion around aspects of dual use governance. The process could provide leverage for engaging with a wider community of actors who could subsequently relay their experiences to others in their respective organizations. The series of regional workshops on the implications of science and technology for the Biological and Toxin Weapons Convention (BWC) convened with support from the European Union might provide an example.⁶

Engaging the Private Sector

Several participants mentioned the role of the private sector in determining norms of practice and highlighted the need for better engagement with this community—including those funding and insuring life sciences research. Suggestions to enhance private-sector engagement in dual use governance included incentives and levers that would be effective, such as framing biosecurity as a business case to industry. Reputational risk was one possible lever identified by participants, who suggested that gene synthesis companies and related organizations had established the IGSC to screen synthetic gene orders for regulated pathogen sequences, in part, because of concerns over reputational risks.⁷

Industry association meetings were also suggested as a useful

⁶ Further information is available at UNOG, “Project 2: Interaction with non-governmental stakeholders on science and technology.” Available at [https://www.unog.ch/80256EE600585943/\(httpPages\)/F5CE37B03894C50EC125809E0057420F?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/F5CE37B03894C50EC125809E0057420F?OpenDocument) (accessed September 5, 2018).

⁷ See IGSC. Available at <https://genesynthesisconsortium.org> (accessed September 5, 2018).

intervention point for discussing dual use governance and moving private-sector engagement forward. Another proposed approach was organizing meetings between public- and private-sector actors to analyze dual use case studies to identify where effective interventions could have been made. Participants also suggested that industry meetings could help in understanding the likely impacts of prospective interventions among a range of life sciences stakeholder communities before money was spent on their implementation.

Engaging Additional Communities: Dialogues with Do-It-Yourself (DIY) Biology and the Public

Although the workshop was focused on life sciences research in settings such as universities, several participants raised the need to engage with members of community laboratories and DIY biology. The Open Philanthropy Project was cited for its support of more projects on biosafety and biosecurity practices targeted to such groups, such as the work being done by iGEM. Similarly, several participants emphasized the need for sustained dialogue and engagement between the life sciences and general public in order to ensure that issues of dual use were not subject to misinformation, manipulation, or alarmism. In some cases, journalists could be briefed prior to publication to ensure a more nuanced understanding around potentially alarming research. Some participants also suggested that a process of public dialogue on dual use and biosecurity could benefit from lessons learned about public engagement from other fields.

Networks of Networks

A wide range of international and regional organizations and networks could play roles in addressing issues related to dual use governance. Several participants noted that the convening capacity of international meetings had proven useful in bringing networks together to move issues forward. One example was the 2005 discussions on codes of conduct under the BWC described in Chapter 3, which resulted in several national and international scientific organizations developing and disseminating an actual code or a set of principles to underlie one. Some participants suggested that the BWC and other international organizations might aid in broadening engagement on dual use governance by bringing together networks of stakeholders. They identified a number of relevant networks for furthering dual use governance of the life sciences, including the European Biosecurity Regulators Forum and the International Expert

Group of Biosafety and Biosecurity Regulators for government officials, and the IAP and international unions for the scientific community.

EDUCATION

The topic of education received considerable attention over the course of the meeting. During the breakout sessions, a number of concrete initiatives on dual use education from around the globe over the past decade were discussed, including activities in Argentina, Australia, Canada, China, Egypt, Germany, Malaysia, Morocco, Pakistan, Switzerland, and Ukraine, among others (Australia et al., 2011; NRC, 2011b; see also Chapter 3 and Appendix E).

Educational Capacity

Participants with experience in developing and undertaking education efforts emphasized that how education is conducted is important to its effectiveness. These participants found particular success using active learning methods and team-based learning exercises. However, they also identified continuing challenges, including the need for sustained effort, the need to assess the effectiveness and impact of activities, the lack of staff trained to teach this aspect of responsible science, and the lack of time lecturers and teachers had to dedicate to understanding this topic.⁸ To help overcome these challenges, this group of participants identified a need to foster academic networks for promoting education and training on biosecurity and dual use; younger scientists were also noted as key in the delivery of education in a sustainable manner. Building such capacity will also require mechanisms to duly credit and reward faculty for attention to dual use governance in the life sciences, they noted.

Should Education Be Mandatory?

Several participants argued that education was more effective when it was mandated and/or supported by the government. On this basis, some argued for comprehensive, mandatory biosecurity education throughout the career cycle of life scientists. However, others argued that earlier enthusiasm for extensive, mandatory education about dual use issues for life scientists had diminished. This was, in part, because although a general awareness of the potential for misuse should be part of the social responsibility of life scientists, some argued that only those involved in

⁸ See NRC (2011b) for a comprehensive discussion of these issues.

high-containment laboratory work required an in-depth knowledge of dual use risks. Moreover, academic curricula are already crowded and it seemed more practical to fit dual use modules into existing courses. Participants commented that scientists already receive information on issues such as animal care and use, environmental protection, and sexual harassment, among others, without always resorting to comprehensive, mandatory measures. As such, it might be possible to integrate discussions of dual use governance into a unified education process that addresses responsibilities of scientists and encourages thinking beyond work on the bench.

Educational Materials

Participants' experiences with educational materials suggested they were most effective when using concrete real-life examples that resonated with the local context. Some participants identified limited access to context-relevant materials, including active learning materials, as a barrier to further work on education. This could be achieved through the development of databases and one-stop centers for information and online teaching materials, such as the International Network on Biotechnology being developed by the UN Interregional Crime and Justice Research Institute. They also stressed the need to improve the accessibility of relevant educational materials through translation into at least the six official UN languages and whenever possible into local languages as well.

Codes of Ethics and Conduct

The topic of codes of ethics, conduct, and practice was frequently linked with the discussions of education. Codes of various types have been one of the most commonly undertaken dual use governance activities. A number of participants saw codes as important complements to education and an area in which there had been some progress since 2005. Multiple examples of codes were identified, including those of China, Cuba, Germany, Indonesia, Japan, Malaysia, the Netherlands, Pakistan, Switzerland, and the United States. In addition, some industry groups and DIY groups have codes as well. Some participants argued that codes worked well for the medical profession, where students were encouraged to consider the relevance and application of the Hippocratic Oath throughout their studies and beyond. However, others pointed to the lack of empirical data on whether codes work, with one participant suggesting that, to be effective, codes needed to be translated into measurable action in the workplace, adding that there is little point trying to implement codes of conduct without an organizational culture that views such codes

as important. Other participants laid emphasis on the value of the process of formulating such codes in a way that was culturally sensitive; the process of discussing what should be included in a code can be viewed as an educational exercise. Yet, others stressed the importance of making individuals aware of existing codes.

LOOKING AHEAD: BUILDING SUCCESS AND SUSTAINABILITY IN DUAL USE GOVERNANCE

Developing Evidence-Based Policies

A number of participants noted the need to develop evidence-based policies and strategic approaches to biosecurity. Multiple countries, universities, and nongovernmental organizations have now undertaken governance efforts; although the landscape can seem like a patchwork of activities, these efforts provide a base that can be built on to draw lessons, disseminate information on successful models, and improve coordination. Developing and building in assessment and gap analysis mechanisms to support evidence-based reporting would be useful, recognizing that one would be assessing the contributions of specific measures to mid-level goals since it would generally not be possible to “prove” that any initiative directly prevented the misuse of life sciences research. Although the importance of an evidence-based approach to governance was noted, a number of participants emphasized that it is unrealistic to expect a perfect, comprehensive policy system from the beginning. Rather, these participants suggested it was valuable to start somewhere, usually by implementing targeted policies and partial solutions that national governments and research communities could accept while enabling oversight mechanisms to evolve. Engaging the affected communities in the development of policies and recognizing the complementary roles of self-governance were also considered essential parts of the growth of effective governance.

Participants suggested such an approach is particularly important in order to seed ideas and awareness as science and technology continue to progress, contributing to a system that could be proactive in identifying potential security concerns that may arise from new developments. The Neuroenhancement, Responsible Research, and Innovation project described in Chapter 2 is an example of such an anticipatory approach, in this case to emerging concerns related to neuroscience. Similarly, the promulgation of norms and principles that set what is acceptable behavior and what it means to be a responsible scientist with regard to biosecurity help form a foundation as new research emerges and existing systems may need to adapt.

Assessment and Evaluation

Several participants noted that there is little empirical evidence of what works and what does not with regard to the implementation of dual use governance measures, including the foundational aspects of education, codes, norm formation, and fostering a culture of scientific responsibility around dual use. Furthermore, what works well in one context may not work as effectively in another. Some metrics for assessing the immediate, short-term impacts of education and training have been developed. However, these metrics would need to be further developed, tested, and refined within the context of broader evaluation methodologies for systematically monitoring progress and assessing results. A number of participants highlighted this as an area requiring further work.

Sustainability

The sustainability of governance activities and initiatives was widely seen as essential to longer-term success. A participant provided an example of one project that built substantial networks over the course of the project lifetime, only to see them fade away once the project concluded. Participants therefore stressed the need to build in mechanisms for the sustainability of networks and project activities, including funding for the transition, as part of planning the initiatives.

CLOSING REMARKS

The workshop convened scientific and policy experts who brought perspectives from many types of governance activities and from multiple countries. The format was designed to consider these perspectives in the context of individual participants' experience and expertise rather than to formulate specific conclusions and recommendations. From this process several broad points consistently emerged. Governance of life sciences research that raises dual use concerns is likely to require a complex and layered system that occurs at multiple stages across the research process. There are thus roles for a range of stakeholders, who may be best positioned to conduct different types of activities. Such stakeholder communities can include government policy makers, research-conducting institutions, practicing researchers from academia and industry, biosafety officers, laboratory risk management professionals, journal publishers, specialists in education and outreach, and many others. Creating effective systems for dual use life sciences governance is not a simple task, and it is important to take the national context of priorities, concerns, incentive systems, and government, research, and educational structures into account when developing the specific practices that will work well.

However, it was also seen as particularly valuable to share models and information, to build networks, and to continue to move toward common understandings. To this end, having places for ongoing discussions at the national, regional, and international levels continues to be important, as is moving toward governance and research oversight systems that can be proactive, rather than reactive, in anticipating potential security concerns. Finally, a number of concrete suggestions for next steps to support the governance of dual use life sciences research arose during the workshop. Table 4-3 provides examples of these ideas.

TABLE 4-3 Suggestions for Specific Actions Arising from Workshop Discussions

Category	Ideas and Next Steps Suggested at the Workshop
Provide Venues to Further Dual Use Discussions	Encourage existing multilateral forums on emerging science and technology to incorporate and discuss the issue of dual use life sciences research. Consider convening a regular event, workshop, or interest group to discuss issues in the governance of dual use life sciences research.
Build Shared Understandings of Key Governance Components	Foster shared definitions of what is encompassed by dual use life sciences research as well as understanding across languages (where there can be differences in terminology, for example). While the details will vary with context, foster common understandings of essential elements that could be included in national systems for governance and oversight of dual use life sciences research (such as those identified in Table 4-1).
Produce Materials and Provide Resources	Compile and analyze principles for governance of research from existing sources. From these, develop a set of principles for the governance of dual use life sciences research. Assemble systematic descriptions of national dual use oversight systems to foster analysis and comparative discussions. Circulate a discussion paper among networks to orient diverse communities to the topic of dual use life sciences research and to continue to foster development of common understandings and approaches. Assemble teaching resources and case examples. Create an informational video with key messages.

continued

TABLE 4-3 Continued

Category	Ideas and Next Steps Suggested at the Workshop
Establish a Clearinghouse or Information Hub	Provide a virtual space that can function as a one-stop shop to share materials and information and to connect stakeholders.
Build Networks	Identify and foster champions who can promote awareness of dual use among their national scientific communities and government agencies. Such champions might serve as points of contact in each country.
Incorporate Dual Use Guidance into the Programs of Work of Other Organizations	A number of organizations and networks that do not have a primary focus on biosecurity may still be relevant to addressing aspects of this broad issue. Include information or guidance on dual use life sciences research where appropriate, for example, in reports and guidelines produced by the World Health Organization, the World Organisation for Animal Health, the Food and Agriculture Organization of the United Nations, the UN Education, Scientific and Cultural Organization, scientific professional societies, and other organizations.
Improve Policy Options and Implementation	<p>Incorporate social sciences expertise into the process of developing and implementing life sciences governance policies.</p> <p>View research oversight as a “Design-Build-Test-Learn” cycle (an approach common in engineering fields) and discuss implementation, lessons learned, and how to adjust the system on a more regular basis.</p> <p>Convene those involved in publication and dissemination of scientific research to address dual use practices in an era of prepublication.</p> <p>Further discuss the changing technical landscape of the life sciences and how dual use oversight systems can prepare (including advances in sequencing and synthesis technologies, use of biofoundries, the role of DIY biology, potential advances in technical mitigation controls, and others).</p>

References

- Academy of Science of South Africa. 2015. *The State of Biosafety and Biosecurity in South Africa*. Pretoria: Academy of Science of South Africa.
- Academy of Science of South Africa. 2018. *The State of Laboratory Biosafety and Biosecurity in the Southern African Development Community (SADC) Region*. Pretoria: Academy of Science of South Africa.
- Amunavi, P. 2018. Biosecurity experts urge universities to secure biomaterials. *Africa Science News*. January 17. Available at <http://africasciencenews.org/biosecurity-experts-urge-universities-to-secure-biomaterials>; accessed August 17, 2018.
- Anisimov, A. P. 1999. Molecular-genetic mechanisms of the formation and functional significance of the capsule of *Yersinia pestis*. Unpublished dissertation. Available at https://www.researchgate.net/publication/256288214_Molecular-genetic_mechanisms_of_the_formation_and_functional_significance_of_the_capsule_of_Yersinia_pestis_Molekularno-geneticeskie_mehanizmy_obrazovania_i_funkcionalnaa_znacimost_kapsuly_Yersinia_pe; accessed July 26, 2018.
- Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland, and the United States of America. 2011. Possible approaches to education and awareness-raising among life scientists. BWC/CONF.VII/WP.20. Available at <http://dag.un.org/handle/11176/292381>; accessed October 2, 2018.
- Australian Government Department of Defence. 2016. Australian Export Controls and the Life Sciences. Available at http://www.defence.gov.au/ExportControls/_Master/docs/Australian_export_controls_and_Life_Sciences.pdf; accessed August 30, 2018.
- Bard, I., G. Gaskell, A. Allansdottir, R. Vieira da Cunha, P. Eduard, J. Hampel, E. Hildt, C. Hofmaier, N. Kronberger, S. Laursen, A. Meijknecht, S. Nordal, A. Quintanilha, G. Revuelta, N. Saladié, J. Sándor, J. Borlido Santos, S. Seyringer, I. Singh, H. Somsen, W. Toonders, H. Torgersen, V. Torre, M. Varju, and H. Zwart. 2018. Bottom up ethics: Neuroenhancement in education and employment. *Neuroethics* 11:309. Available at <https://doi.org/10.1007/s12152-018-9366-7>; accessed August 30, 2018.

- Basbug, G., A. Cavicchi, and S. Silbey. 2016. What do environmental health and safety management systems do? Longitudinal evidence from academic research laboratories. Working Paper. Eastern Sociological Society, Boston.
- BBSRC (Biotechnology and Biological Sciences Research Council), MRC (Medical Research Council), and WT (Wellcome Trust). 2015. *BBSRC, MRC and Wellcome Trust position statement on dual use research of concern and research misuse*. Available at <https://wellcome.ac.uk/sites/default/files/wtp059491.pdf>; accessed August 5, 2018.
- Bruns, H. C. 2009. Leveraging functionality in safety routines: Examining the divergence of rules and performance. *Human Relations* 62(9):1399–1426. Available at <https://doi.org/10.1177/0018726709339130>; accessed August 30, 2018.
- BWC (Biological and Toxin Weapons Convention). 1972. Text of the Convention. Available at [https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/C4048678A93B6934C1257188004848D0/\\$file/BWC-text-English.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/C4048678A93B6934C1257188004848D0/$file/BWC-text-English.pdf); accessed July 25, 2018.
- BWC. 2005. Report of the Meeting of Experts. BWC/MSP/2005/MX/3. Available at http://www.un.org/ga/search/view_doc.asp?symbol=BWC/MSP/2005/MX/3; accessed October 4, 2018.
- Casman, E., B. Fischhoff, C. Palmgren, M. Small, and F. Wu. 2000. Integrated risk model of a drinking waterborne *Cryptosporidiosis* outbreak. *Risk Analysis* 20:493–509.
- Cello, J., A. V. Paul, and E. Wimmer. 2002. Chemical synthesis of Poliovirus cDNA: Generation of infectious virus in the absence of natural template. *Science* 297(5583):1016–1018. Available at <https://doi.org/10.1126/science.1072266>; accessed September 4, 2018.
- Chau, D.-M., L. C. Chai, and A. Veerakumarasivam, Eds. 2018. Malaysian Educational Module on Responsible Conduct of Research. Academy of Sciences Malaysia. Available at <http://rmic.upsi.edu.my/?p=154890>; accessed July 22, 2018.
- Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Italy, Mexico, and Spain. 2014. Code of Conduct for Scientists. BWC/MSP/2014/WP.6. Available at <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G14/232/57/pdf/G1423257.pdf>; accessed August 10, 2018.
- China. 2015. Proposal for the Development of the Template of Biological Scientist Code of Conduct under the Biological Weapons Convention. BWC/MSP/2015/WP.9. Available at <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G15/285/28/pdf/G1528528.pdf>; accessed August 23, 2018.
- China and Pakistan. 2016. Proposal for the Development of a Model Code of Conduct for Biological Scientists under the Biological Weapons Convention. BWC/CONF.VIII/WP.30. Available at <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G16/252/49/pdf/G1625249.pdf>; accessed August 23, 2018.
- Council of Science Editors. 2018. White Paper on Promoting Integrity in Scientific Journal Publications. Available at <https://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics>; accessed August 6, 2018.
- DFG (German Research Foundation). 2013. Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins. Available at http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2013/130313_verhaltenscodex_dual_use_en.pdf; accessed August 17, 2018.
- DFG and German National Academy of Sciences Leopoldina. 2014. Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security Relevant Research. Available at https://www.eurekalert.org/pub_releases/2014-06/1-dal062614.php; accessed August 16, 2018.
- DiEuliis, D., K. Berger, and G. Gronvall. 2017. Biosecurity implications for the synthesis of horsepox, an *Orthopoxvirus*. *Health Security* 15(6):629–637. Available at <https://doi.org/10.1089/hs.2017.0081>; accessed September 4, 2018.

- Dowall, S. D., D. A. Matthews, I. García-Dorival, I. Taylor, J. Kenny, C. Hertz-Fowler, N. Hall, K. Corbin-Lickfett, C. Empig, K. Schlunegger, J. N. Barr, M. C. Carroll, R. Hewson, and J. A. Hiscox. 2014. Elucidating variations in the nucleotide sequence of Ebola virus associated with increasing pathogenicity. *Genome Biology* 15(11):540. Available at <https://doi.org/10.1186/s13059-014-0540-x>; accessed September 4, 2018.
- EBRF (European Biosecurity Regulators Forum). 2016. Securing Immaterial Technology with Dual-Use Potential. Working paper. June 21. Available at http://www.ebrf.eu/documents/EBRF_workingpaper_210616.pdf; accessed August 11, 2018.
- Edwards, D., J. Hanes, G. Caponetti, J. Hrkach, A. Ben-Jebria, M. L. Eskew, J. Mintzes, D. Deaver, N. Lotan, and R. Langer. 1997. Large porous particles for pulmonary drug delivery. *Science* 276(5320):1868–1872. Available at <https://doi.org/10.1126/science.276.5320.1868>; accessed September 4, 2018.
- European Commission. Undated. Guidance Note—Potential Misuse of Research. Available at http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf; accessed August 5, 2018.
- FDA (U.S. Food and Drug Administration). 2013. Structured Approach to Benefit-Risk Assessment for Drug Regulatory Decision Making. Draft PDUFA V Implementation Plan (2/13). FY2013–2017. Available at <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm329758.pdf>; accessed August 1, 2018.
- Fischhoff, B. 2013. The sciences of science communication. *Proceedings of the National Academy of Sciences of the United States of America* 110(Supplement 3):14033–14039. Available at <https://doi.org/10.1073/pnas.1213273110>; accessed October 2, 2018.
- Fischhoff, B. 2015. The realities of risk-cost-benefit analysis. *Science* 350(6260):527 and aaa6516. Available at <https://doi.org/10.1126/science.aaa6516>; accessed September 4, 2018.
- Fischhoff, B., and J. D. Kadavy. 2011. *Risk: A Very Short Introduction*. Oxford, UK: Oxford University Press.
- Fischhoff, B., W. Bruine de Bruin, U. Guvenc, D. Caruso, and L. Brilliant. 2006. Analyzing disaster risks and plans: An avian flu example. *Journal of Risk and Uncertainty* 33:133–151.
- Fischhoff, B., N. T. Brewer, and J. S. Downs. 2011. Communicating Risks and Benefits: An Evidence-Based User’s Guide. Available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM268069.pdf>; accessed September 4, 2018.
- Galimand, M., A. Guiyoule, G. Gerbaud, B. Sasoamanana, S. Chanteau, E. Carniel, and P. Courvalin. 1997. Multidrug resistance in *Yersinia pestis* mediate by a transferable plasmid. *New England Journal of Medicine* 337(10):677–681.
- Gaskell, G., I. Bard, A. Allansdottir, R. Vieira da Cunha, P. Eduard, J. Hampel, E. Hildt, C. Hofmaier, N. Kronberger, S. Laursen, A. Meijknecht, S. Nordal, A. Quintanilha, G. Revuelta, N. Saladié, J. Sándor, J. Borlido Santos, S. Seyringer, I. Singh, H. Somsen, W. Toonders, H. Torgersen, V. Torre, M. Varju, and H. Zwart. 2017. Public views on gene editing and its uses. *Nature Biotechnology* 35:1021–1023. Available at <https://doi.org/10.1038/nbt.3958>; accessed September 4, 2018.
- Geffers, J., C. Beaudry, H-C. Yang, F. Huang, O. Phanraska, M. Dominik, Y-C. Lin, M-C. Huang, S. Komai, K. Lorimer, W. Piyawattanametha, P. Saengchanti, H. Saleh, B. Tagg, and A. Veerakumarasivam. 2017. Global State of Young Scientists (GloSYS) in ASEAN: Creativity and Innovation of Young Scientists in ASEAN. Halle (Saale), Germany: Global Young Academy. Available at https://globallyoungacademy.net/wp-content/uploads/2017/01/GloSYS-in-ASEAN_webversion.pdf; accessed October 2, 2018.
- German Ethics Council (Deutscher Ethikrat). 2014. *Biosecurity—Freedom and Responsibility of Research*. Berlin: German Ethics Council.

- German Government. 2018. Germany's Best Practice in Handling (Bio)Security-Relevant Research: Self-Governance Organized by the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG). BWC/2018/MX.2/WP.1. Available at <http://www.undocs.org/bwc/msp/2018/mx.2/wp.1>; accessed August 17, 2018.
- Gray, G. C., and S. S. Silbey. 2014. Governing inside the organization: Interpreting regulation and compliance. *American Journal of Sociology* 120(1):96–145. Available at <http://www.ncbi.nlm.nih.gov/pubmed/25705781>; accessed September 4, 2018.
- Haga, S. B., and H. F. Willard. 2006. Defining the spectrum of genome policy. *Nature Reviews Genetics* 7:966–972.
- HHS (U.S. Department of Health and Human Services). 2010. Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA. Available at <https://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf>; accessed October 2, 2018.
- HHS. 2013. 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. Available at <https://www.phe.gov/s3/dualuse/Pages/HHSh5n1Framework.aspx>; accessed October 2, 2018.
- HHS. 2017. Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens. Available at <https://www.phe.gov/s3/dualuse/Documents/p3co.pdf>; accessed October 2, 2018.
- Huising, R. 2015. To hive or to hold? Producing professional authority through scut work. *Administrative Science Quarterly* 60:263–299.
- Huising, R., and S. S. Silbey. 2013. Constructing consequences for noncompliance. *Annals of the American Academy of Political and Social Science* 649(1):157–177. Available at <https://doi.org/10.1177/0002716213492633>; accessed September 4, 2018.
- Huising, R., and S. S. Silbey. 2018. From nudge to culture and back again: Coalface governance in the regulated organization. *Annual Review of Law and Social Science* 14:1. Available at <https://doi.org/10.1146/annurev-lawsocsci-110615-084716>; accessed October 2, 2018.
- IAP (InterAcademy Panel on International Issues). 2005. *IAP Statement on Biosecurity*. Available at <http://www.interacademies.org/13912/IAP-Statement-on-Biosecurity>; accessed October 4, 2018.
- ICSU (International Council for Science). 2014. *Freedom, Responsibility and Universality of Science*. Paris: ICSU.
- IGSC (International Gene Synthesis Consortium). 2017. Harmonized Screening Protocol© v2.0. Available at <https://genesynthesisconsortium.org/wp-content/uploads/IGSCHARmonizedProtocol11-21-17.pdf>; accessed October 2, 2018.
- Imai, M., T. Watanabe, M. Hatta, S. C. Das, M. Ozawa, K. Shinya, G. Zhong, A. Hanson, H. Katsura, S. Watanabe, C. Li, E. Kawakami, S. Yamada, M. Kiso, Y. Suzuki, E. A. Maher, G. Neumann, and Y. Kawaoka. 2012. Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets. *Nature* 486(7403):420–428. Available at <https://doi.org/10.1038/nature10831>; accessed October 2, 2018.
- Indonesia, Malaysia, the Netherlands, and the United States. 2015. National Measures to Address Dual Use Research: Submitted to the 2015 BWC Meeting of Experts by Indonesia, Malaysia, the Netherlands and the United States of America. Available at [https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/314CF989547D74FAC1257EA0003B2877/\\$file/WP+by+NL_MY_US_INDO_WP_National+Measures+to+Address+Dual+Use+Research_150812.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/314CF989547D74FAC1257EA0003B2877/$file/WP+by+NL_MY_US_INDO_WP_National+Measures+to+Address+Dual+Use+Research_150812.pdf); accessed October 7, 2018.
- IOM (Institute of Medicine). 1999. *Toward Environmental Justice: Research, Education, and Health Policy Needs*. Washington, DC: National Academy Press.

- Israel National Security Council and Israel Academy of Sciences and Humanities. 2008. *Biotechnological Research in an Age of Terrorism*. Jerusalem: Israel National Security Council and Israel Academy of Sciences and Humanities.
- Jackson, R. J., A. J. Ramsay, C. D. Christensen, S. Beaton, D. F. Hall, and I. A. Ramshaw. 2001. Expression of mouse interleukin-4 by a recombinant Ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. *Journal of Virology* 75(3):1205–1210. Available at <https://doi.org/10.1128/JVI.75.3.1205-1210.2001>; accessed September 4, 2018.
- Journal Editors and Authors Group. 2003. Statement on scientific publication and security. *Science* 299:1149. Available at <http://science.sciencemag.org/content/sci/299/5610/1149.full.pdf>; accessed October 3, 2018.
- Kahneman, D. 2011. *Thinking, Fast and Slow*. New York: Strauss.
- Kaiser, J. 2014. White House orders biosafety review at federal labs. *Science*. August 28. Available at <http://www.sciencemag.org/news/2014/08/white-house-orders-biosafety-review-federal-labs>; accessed August 23, 2018.
- Kerr, P. J., H. Perkins, B. Inglis, R. Stagg, E. McLaughlin, S. Collins, and B. van Leeuwen. 2004. Expression of rabbit IL-4 by recombinant myxoma viruses enhances virulence and overcomes genetic resistance to myxomatosis. *Virology* 324(1):117–128. Available at <https://doi.org/10.1016/j.virol.2004.02.031>; accessed September 4, 2018.
- KNAW (Royal Netherlands Academy of Arts and Sciences). 2008. *A Code of Conduct for Biosecurity*. Report by the Biosecurity Working Group. Amsterdam: Royal Netherlands Academy of Arts and Sciences. Available at <https://knaw.nl/en/news/publications/a-code-of-conduct-for-biosecurity>; accessed October 4, 2018.
- Lentzos, F. 2015. Dual use in biology and biomedicine. Background paper commissioned by the Nuffield Council on Bioethics. Available at <http://nuffieldbioethics.org/wp-content/uploads/Background-paper-2016-Dual-use.pdf>; accessed October 3, 2018.
- Migone, A., and M. Howlett. 2009. Classifying biotechnology-related policy, regulatory and innovation regimes: A framework for the comparative analysis of genomics policy-making. *Policy and Society* 28(4):267–278. Available at <https://doi.org/10.1016/j.polsoc.2009.09.002>; accessed September 4, 2018.
- Millett, P. 2017. Gaps in the International Governance of Dual-Use Research of Concern. In *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*. Washington, DC: The National Academies Press. Available at <https://www.nap.edu/catalog/24761>; accessed October 4, 2018.
- Morgan, M. G. 2017. *Theory and Practice in Policy Analysis: Including Applications in Science and Technology*. New York: Cambridge University Press.
- NASEM (National Academies of Sciences, Engineering, and Medicine). 2016. *Gain-of-Function Research: Summary of the Second Symposium, March 10–11, 2016*. Washington, DC: The National Academies Press.
- NASEM. 2017a. *Human Genome Editing: Science, Ethics, and Governance*. Washington, DC: The National Academies Press.
- NASEM. 2017b. *Building Communication Capacity to Counter Infectious Disease Threats: Proceedings of a Workshop*. Washington, DC: The National Academies Press.
- NASEM. 2017c. *Communicating Science Effectively: A Research Agenda*. Washington, DC: The National Academies Press.
- NASEM. 2017d. *Foundational Cybersecurity Research: Improving Science, Engineering, and Institutions*. Washington, DC: The National Academies Press.
- NASEM. 2017e. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*. Washington, DC: The National Academies Press.
- NASEM. 2017f. *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*. Washington, DC: The National Academies Press.

- NASEM. 2018. *Biodefense in the Age of Synthetic Biology*. Washington, DC: The National Academies Press.
- Noyce, R. S., S. Lederman, and D. H. Evans. 2018. Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. *PLOS ONE* 13(1):e0188453. Available at <https://doi.org/10.1371/journal.pone.0188453>; accessed September 4, 2018.
- NRC (National Research Council). 2004. *Biotechnology Research in an Age of Terrorism*. Washington, DC: The National Academies Press.
- NRC. 2011a. *Intelligence Analysis for Tomorrow: Advances from the Behavioral and Social Sciences*. Washington, DC: The National Academies Press.
- NRC. 2011b. *Challenges and Opportunities for Education About Dual Use Issues in the Life Sciences*. Washington, DC: The National Academies Press.
- NRC. 2013. *Perspectives on Research with H5N1 Avian Influenza: Scientific Inquiry, Communication, Controversy*. Washington, DC: The National Academies Press.
- NRC. 2015. *Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop*. Washington, DC: The National Academies Press.
- NSABB (National Science Advisory Board for Biosecurity). 2016. Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research. Washington, DC: National Institutes of Health. Available at https://osp.od.nih.gov/wp-content/uploads/2016/06/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf; accessed September 23, 2018.
- OECD (Organisation for Economic Co-operation and Development). 2007. *OECD Best Practice Guidelines on Biosecurity for BRCS (Biological Resource Centres)*. Paris: Organisation for Economic Co-operation and Development. Available at <http://www.oecd.org/health/biotech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm>; accessed September 5, 2018.
- OIE (World Organisation for Animal Health). 2015a. *Biological Threat Reduction Strategy: Strengthening Global Biological Security*. Paris: OIE.
- OIE. 2015b. *Biological Threat Reduction: Proceedings of the First OIE Global Conference on Biological Threat Reduction*. Paris: OIE.
- Paarlberg, R. L. 2000. *Governing the GM Crop Revolution: Policy Choices for Developing Countries*. Washington, DC: International Food Policy Research Institute.
- Rappert, B. 2004. *Towards a Life Sciences Code: Countering the Threats from Biological Weapons*. Bradford Briefing Papers (2nd Series), No. 13. Bradford Disarmament Research Centre, University of Bradford. Available at <https://bradscholars.brad.ac.uk/handle/10454/795>; accessed August 23, 2018.
- RKI (Robert Koch Institute). 2013. Dual Use Potential of Life Sciences Research—Code of Conduct for Risk Assessment and Risk Mitigation (English version, June 14). Available at https://www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html; accessed August 24, 2018.
- Russell, C., J. M. Fonville, A. E. X. Brown, D. F. Burke, D. L. Smith, S. L. James, S. Herfst, S. van Boheemen, M. Linster, E. J. Schrauwen, L. Katzelnick, A. Mosterin, T. Kuiken, E. Maher, G. Neumann, A. D. M. E. Osterhaus, Y. Kawaoka, R. A. M. Fouchier, and D. J. Smith. 2012. The potential for respiratory droplet-transmissible A/H5N1 influenza virus to evolve in a mammalian host. *Science* 336(6088):1541–1547.
- Science Council of Japan. 2013. *Statement: Code of Conduct for Scientists*. Revised Version, January 25, 2013. Available at http://www.scj.go.jp/en/report/Code_of_Conduct_for_Scientists.pdf; accessed October 4, 2018.
- Second World Conference on Research Integrity. 2010. Singapore Statement. Available at <https://wcrif.org/statement>; accessed August 27, 2018.

- Shinwari, Z. K. (ed.). 2015. *Dual-Use Education Concerns in Biotechnology: Pakistani Perspective*. Islamabad: Pakistan Academy of Sciences. Available at <http://paspk.org/wp-content/uploads/2015/12/Dual-Use-of-Education.pdf>; accessed August 23, 2018.
- Silbey, S. S. 2009. Taming Prometheus: Talk about safety and culture. *Annual Review of Sociology* 35:341–369.
- Smith-Doerr, L., and I. Vardi. 2015. Mind the gap: Formal ethics policies and chemical scientists' everyday practices in academia and industry. *Science, Technology & Human Values* 40(2):176–198.
- Stilgoe, J., R. Owen, and P. Macnaghten. 2013. Developing a framework for responsible innovation. *Research Policy* 42(9):1568–1580.
- Swiss Academies of Arts and Sciences. 2017. *Misuse Potential and Biosecurity in Life Sciences Research*. Swiss Academies Reports 12(3). Available at <https://www.sapea.info/sapea-publications>; accessed October 4, 2018.
- Thaler, R. H., and C. R. Sunstein. 2008. *Nudge: Improving Decisions about Health, Wealth, and Happiness*. London, UK: Penguin Books.
- Tumpey, T. M., C. F. Basler, P. V. Aguilar, H. Zeng, A. Solórzano, D. E. Swayne, and A. García-Sastre. 2005. Characterization of the reconstructed 1918 Spanish influenza pandemic virus. *Science* 310(5745):77–80. Available at <https://doi.org/10.1126/science.1119392>; accessed September 4, 2018.
- UK (United Kingdom) Home Office. 2018. Biological Security Strategy. Available at <https://www.gov.uk/government/publications/biological-security-strategy>; accessed August 12, 2018.
- UN (United Nations) Security Council. 2004. Text of UN Security Council Resolution 1540. Available at [http://www.un.org/ga/search/view_doc.asp?symbol=S/RES/1540%20\(2004\)](http://www.un.org/ga/search/view_doc.asp?symbol=S/RES/1540%20(2004)); accessed July 25, 2018.
- UN Security Council. 2016a. Report of the Security Council Committee Established Pursuant to Resolution 1540 (2004). Available at <https://undocs.org/S/2016/1038>; accessed July 25, 2018.
- UN Security Council. 2016b. Text of UN Security Council Resolution 2325. Available at <http://unscr.com/en/resolutions/doc/2325>; accessed July 25, 2018.
- UNESCO (United Nations Educational, Scientific and Cultural Organization). 2017. Recommendation on Science and Scientific Researchers. Available at http://portal.unesco.org/en/ev.php-URL_ID=49455&URL_DO=DO_TOPIC&URL_SECTION=201.html; accessed August 10, 2018.
- U.S. Government. 2012. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Available at <https://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf>; accessed July 22, 2018.
- U.S. Government. 2014a. United States Government Policy for Institutional Oversight of Life Sciences DURC. Available at <https://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx>; accessed July 29, 2018.
- U.S. Government. 2014b. Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern. Prepared by the National Institutes of Health on behalf of the U.S. Government. Available at <https://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>; accessed July 29, 2018.
- U.S. Government. 2014c. Report of the Federal Experts Security Advisory Panel. Available at <https://www.phe.gov/s3/Documents/fesap.pdf>; accessed August 23, 2018.
- U.S. Government. 2015. Implementation of Recommendations of the Federal Experts Security Advisory Panel and the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR). Available at <https://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf>; accessed August 23, 2018.

- U.S. Government. 2017. Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight. Available at <https://www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx>; accessed August 5, 2018.
- von Schomberg, R. 2013. A Vision of Responsible Research and Innovation. In *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, edited by R. Owen, J. Bessant, and M. Heintz. New York: Wiley. Available at <https://doi.org/10.1002/9781118551424.ch3>; accessed September 4, 2018.
- Weyant, R. S. 2013. The International Group of Experts on Biosafety and Biosecurity Regulation. Presentation available at <http://www.eagleson.org/wp-content/uploads/2014/02/W0805.pdf>; accessed August 11, 2018.
- WHO (World Health Organization). 2004. *Laboratory Biosafety Manual*, 3rd ed. Geneva: WHO. Available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en; accessed September 5, 2018.
- WHO. 2005. *Life Science Research: Opportunities and Risks for Public Health*. Geneva: WHO. Available at <http://www.who.int/ethics/Life%20Science%20Research.pdf>; accessed October 4, 2018.
- WHO. 2007. *Scientific Working Group on Life Science Research and Global Health Security: Report of the First Meeting*. Geneva: WHO.
- WHO. 2010. *Responsible Life Sciences Research for Global Health Security: A Guidance Document*. Geneva: WHO. Available at http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en; accessed October 4, 2018.
- Zwart, H., J. Brenninkmeijer, P. Eduard, L. Krabbenborg, S. Laursen, G. Revuelta, and W. Toonders. 2017. Reflection as a deliberative and distributed practice: Accessing neuro-enhancement technologies via mutual learning exercises (MLEs). *Nanoethics* 11:127. Available at <https://doi.org/10.1007/s11569-017-0287-4>; accessed September 4, 2018.

Appendix A

Agenda

SUNDAY, 10 JUNE

Welcome Reception, Atrium, Croatian Academy of Sciences and Arts

Opening Remarks

Chair: Alemka Markotić, University Hospital for Infectious Diseases Zagreb, Catholic University of Croatia, and Medical Faculty, University of Rijeka

- *Jakša Barbić, Vice President of the Croatian Academy of Sciences and Arts*
- *Marko Pećina, Secretary of the Department of Medical Sciences of the Croatian Academy of Sciences and Arts*
- *Alemka Markotić, President of the Croatian Society for Biosafety and Biosecurity*
- *Peter McGrath, Coordinator of the InterAcademy Partnership (IAP)*
- *Jaime Yassif, Program Officer for Biosecurity and Pandemic Preparedness of the Open Philanthropy Project*

MONDAY, 11 JUNE

9:00 **Plenary I, Conference Room, Croatian Academy of Sciences and Arts**

Chair: Sue Meek, Chair of Planning Committee, The Australian National University

- **Welcome** – *Victor Dzau, President of the National Academy of Medicine of the U.S. National Academies of Sciences, Engineering, and Medicine*
- **Introduction to the Goals of the Workshop** – *Sue Meek, Chair of Planning Committee*
 - Map the landscape of recent and current governance activities
 - Understand what has worked, why or why not, and lessons learned; identify gaps and needs and how they might be filled
 - Identify opportunities to promote and sustain the governance of dual use research and concrete actions that can be undertaken in short, medium, and longer terms to take advantage of them
- **The Nature of Governance**
 - Introduction to the concept of governance as a layered system across the research enterprise – *Alta Charo, University of Wisconsin–Madison*
 - Initial comments – *Michele Garfinkel, EMBO*
- **Discussion**

10:15 Break

10:45 **Plenary II – Life Sciences Governance in Action**
Chair: *M. Iqbal Parker, University of Cape Town*

- **Introduction to Recent Life Sciences Examples with Dual Use Implications** – *Piers Millett, iGEM Foundation*
- **Panel: Examples of Life Science Governance Activities, Outcomes and Lessons**
 - *Julia Bowett, Department of Defense Export Control Branch, Australia*
 - *Joseph Kanabrocki, University of Chicago*
 - *Abhi Veerakumarasivam, Sunway University*
 - *Agnes Allansdottir, Toscana Life Sciences Foundation*
- **Discussion** with introductory speaker and panelists

12:30 Lunch

- 14:00 **Plenary III – Introduction to the Breakout Sessions**
Chair: *Robin Fears, European Academies Science Advisory Council (EASAC)*
- **Introduction to Breakout Session #1**
 - **Discussion**
- 14:20 Move to breakout rooms
- 14:30 **Breakout Session #1 – Taking Stock: Where Are We Now?**
The first of three breakout sessions to take place during the workshop will review the landscape of governance efforts that have been undertaken or are currently in progress. Participants are assigned to groups to identify additional examples and to discuss emerging themes. Assignments are in the meeting materials.
- Group A:** Nancy Connell (Chair) and Kathryn Nixdorff (Rapporteur) – *Conference Room*
Group B: Michele Garfinkel (Chair) and Filippa Lentzos (Rapporteur) – *Meeting Room*
Group C: Alejandra Suárez (Chair) and Abhi Veerakumarasivam (Rapporteur) – *Salon*
- Break (15:30–16:00; taken during the session)
- 17:00 Return to plenary room
- 17:15 **Wrap-Up and Plans for Day 2**
Chair: *Peter McGrath, InterAcademy Partnership (IAP)*
- 17:30 Adjourn for the day
- 19:00 **Conference Dinner**

TUESDAY, 12 JUNE

- 9:00 **Plenary IV**
Chair: *Alemka Markotić, University Hospital for Infectious Diseases Zagreb, Catholic University of Croatia, and Medical Faculty, University of Rijeka*

Part 1: Reports from Breakout Session #1

- Reports from breakout sessions
- Discussion

Part 2: Introduction to Breakout Session #2

9:50 Move to breakout rooms; collect coffee or tea on the way

10:10 Breakout Session #2 – Lessons Learned, Gaps, and Opportunities

Breakout session #2 will analyze governance activities that have been conducted in order to discuss what has worked, why or why not, and lessons learned, as well as to identify gaps and needs and how they might be filled. Participants are assigned to groups and will remain with the same group for sessions #2 and #3. Assignments are in the meeting materials.

Group A: Governance at the National Level: Nancy Connell (Chair) and Caitriona McLeish (Rapporteur) – *Conference Room*

Group B: Governance at the Regional and International Level: Michele Garfinkel (Chair) and Catherine Rhodes (Rapporteur) – *Meeting Room*

Group C: Promoting and Sustaining Governance – Norms, Codes, Education and Training, and Outreach: Alejandra Suárez (Chair) and Tatyana Novossioloova (Rapporteur) – *Salon*

12:10 Lunch

13:40 Plenary V

Chair: *Herawati Sudoyo, Eijkman Institute for Molecular Biology*

Part 1: Fostering Change: Insights from the social and behavioral sciences on strategies and processes for promoting and sustaining effective governance.

- *Ruthanne Huising, McGill University*
- *Baruch Fischhoff, Carnegie Mellon University*

- Discussion

Part 2: Reports from Breakout Session #2

- Reports from the morning's breakout session
- Discussion

Part 3: Introduction to Breakout Session #3

- 15:30 Break and move to breakout rooms
- 15:45 **Breakout Session #3 – Looking Ahead: Where Do We Want to Go and How Do We Get There?**
The final breakout session will build on the session #2 discussions. It will focus on identifying opportunities to promote and sustain the governance of dual use research and concrete actions that can be undertaken in short, medium, and longer terms to take advantage of them. Participants remain with their groups from session #2.
- 17:40 Return to plenary room
- 17:50 **Wrap-Up and Plans for Day 3**
Chair: *Peter McGrath, InterAcademy Partnership (IAP)*
- 18:00 Adjourn for the day and **Networking Reception, Atrium, Croatian Academy of Sciences and Arts**

WEDNESDAY, 13 JUNE

- 9:00 **Plenary VI**
Chair: *Sasha Kagansky, Far Eastern Federal University*
- Reports from breakout session #3
 - Discussion
- 10:00 Break
- 10:30 **Plenary VII – Summary of the Meeting**
Chair: *Sue Meek, Chair of Planning Committee*

- Facilitated discussion of breakout session results and workshop themes
- Discussion among all participants, including suggestions for the workshop proceedings

12:15 **Meeting Adjourns**

Appendix B

Participants

Agnes Allansdottir

*Fondazione Toscana Life Sciences
Italy*

Lela Bakanidze

*International Federation of Biosafety
Associations
Georgia*

Maurizio Barbeschi

World Health Organization

Halima Benbouza

*University Batna 1
Algeria*

Rik Bleijs

*National Institute for Public Health
and the Environment
The Netherlands*

Fran Borovečki

*University Hospital Centre Zagreb,
and School of Medicine,
University of Zagreb
Croatia*

Julia Bowett

*Defence Department
Australia*

Katherine Bowman

*U.S. National Academies of Sciences,
Engineering, and Medicine
United States*

Nils Braun

*General Secretariat of Defense and
National Security
France*

Heather Browett

*Wellcome Trust
United Kingdom*

R. Alta Charo

*University of Wisconsin–Madison
United States*

Nancy Connell

*Rutgers University
United States*

Lidija Cvetko Krajinović

*University Hospital for Infectious
Diseases
Croatia*

Malcolm Dando

*University of Bradford
United Kingdom*

Victor Dzau

*National Academy of Medicine
United States*

Mohamed El-Faham

*Bibliotheca Alexandrina
Egypt*

Daniel Feakes

*Implementation Support Unit,
Biological Weapons Convention*

Robin Fears

*European Academies Science
Advisory Council (EASAC)
United Kingdom*

Baruch Fischhoff

*Carnegie Mellon University
United States*

Jonathan Forman

*Organization for the Prohibition of
Chemical Weapons*

Michele Garfinkel

*EMBO
Germany*

Luam Ghebreghiorghis

*Robert Koch Institute
Germany*

Gigi Gronvall

*Johns Hopkins University School of
Public Health
United States*

Line Gylling

*Center for Biosecurity and
Biopreparedness
Denmark*

Alexander Hamilton

*United Nations Interregional Crime
and Justice Research Institute
(UNICRI)*

Alastair Hay

*University of Leeds
United Kingdom*

Elizabeth Hodson

*Pontificia Universidad Javeriana
Colombia*

Ruthanne Huising

*McGill University
Canada*

Jo Husbands

*U.S. National Academies of Sciences,
Engineering, and Medicine
United States*

Alexander (Sasha) Kagansky

*Far Eastern Federal University
Russia*

Tracy Kambara

*Harvard University
United States*

Joseph Kanabrocki

*University of Chicago
United States*

Filippa Lentzos

*Kings College
United Kingdom*

Kenji López Cuevas

*Ministry of Foreign Affairs
Mexico*

Robin Lovell-Badge

*The Francis Crick Institute
United Kingdom*

Alemka Markotić

*University Hospital for Infectious
Diseases Zagreb, Catholic
University of Croatia, and
Medical Faculty, University of
Rijeka
Croatia*

Peter McGrath

*InterAcademy Partnership (IAP)
Italy*

Caitriona McLeish

*University of Sussex
United Kingdom*

Sue Meek

*The Australian National University
Australia*

Lorna Miller

*DSTL Porton Down
United Kingdom*

Piers Millett

*iGEM Foundation
United Kingdom*

Indira Nath

*All India Institute of Medical
Sciences
India*

Kathryn Nixdorff

*Darmstadt University of Technology
Germany*

Tatyana Novossiolova

*Landau Network - Fondazione Volta,
Italy
Centre for the Study of Democracy,
Bulgaria
Italy/Bulgaria*

Luis Ochoa Carrera

*Mexican Biosafety Association and
Institute for Epidemiological
Diagnosis and Reference,
Ministry of Health
Mexico*

Claudia Otto

*ETH Zurich
Switzerland*

Christopher Park

*Department of State
United States*

M. Iqbal Parker

*University of Cape Town
South Africa*

Orakanoke Phanraksa

*National Science and Technology
Development Agency
Thailand*

Wibool Piyawattanametha

*King Mongkut's Institute of
Technology Ladkrabang
Thailand*

Giovanna Pontes

*University of Sussex
Brazil*

James Revill

*University of Sussex
United Kingdom*

Catherine Rhodes

*University of Cambridge
United Kingdom*

Mark Rweyemamu

*Sokoine University of Agriculture
Tanzania*

Marina Šantić

*Faculty of Medicine, University of
Rijeka
Croatia*

Laila Sbabou

*Université Mohammed V – Agdal
Morocco*

Yonat Shemer Avni

*Ben-Gurion University of the Negev
Israel*

Nariyoshi Shinomiya

*National Defense Medical College
Japan*

Zabta Shinwari

*Qarshi University, Lahore
Pakistan*

Christopher Simuntala

*National Biosafety Authority
Zambia*

Alejandra Suárez

*Instituto de Química Rosario –
CONICET Argentina*

Herawati Sudoyo

*Eijkman Institute for Molecular
Biology Indonesia*

Lizeka Tandwa

*University of the Witwatersrand
South Africa*

Christine Uhlenhaut

*World Organisation for Animal
Health (OIE)*

Abhi Veerakumarasivam

*Sunway University
Malaysia*

Carrie Wolinetz

*National Institutes of Health
United States*

Jaime Yassif

*Open Philanthropy Project
United States*

Zhiming Yuan

*Wuhan Institute of Virology, Chinese
Academy of Sciences
China*

Zalini Yunus

*Science & Technology Research
Institute for Defence (STRIDE),
Ministry of Defence
Malaysia*

Weiwen Zhang

Tianjn University

China

Ljiljana Žmak

Croatian Institute of Public Health

and School of Medicine,

University of Zagreb

Croatia

Appendix C

Committee Member Biographies

Sue Meek, Ph.D. (Chair), is Honorary Professor in the Research School of Biology of the Australian National University. She is also the principal of Sue Meek and Associates, which works at the interface of academe, industry, government, and nongovernmental entities to increase awareness and understanding of the economic and social implications of science and technology and to facilitate the conduct, application, and commercialization of research and development. From 2008 to 2016 Dr. Meek was the Chief Executive of the Australian Academy of Science, providing leadership to the Academy Secretariat in developing and delivering programs to promote excellence in scientific research nationally and internationally, to develop and sustain a national scientific culture, and to provide valued independent scientific advice to assist evidence-based policy development. Dr. Meek was previously Australia's inaugural Gene Technology Regulator from December 2001. This statutory appointment was established by the federal government to administer the national regulatory system for the development and use of genetically modified organisms. Prior to this she held various senior state government positions where she was responsible for the development and implementation of policies on science and technology and public-sector intellectual property management, and the administration of grant programs to support innovation and to develop research capability. Dr. Meek has a Ph.D. in marine biology, an M.Sc. in oceanography, and a B.Sc. (Hons) in microbiology. She is an Officer of the Order of Australia, a Fellow of the Australian Institute of Company Directors, and a Fellow of the Australian Academy of Tech-

nological Sciences and Engineering. She is also a member of the board of Bioplatforms Australia Ltd. and a trustee of the International Life Sciences Institute's Research Foundation.

R. Alta Charo, J.D., is the Warren P. Knowles Professor of Law at the University of Wisconsin–Madison, where she teaches bioethics, biotechnology policy, public health law, and torts. Professor Charo (A.B., biology, Harvard University, 1979; J.D., law, Columbia University, 1982) was elected in 2006 to membership in the U.S. National Academy of Medicine (NAM), from which she received the Adam Yarmolinsky medal for service to the U.S. National Academies of Sciences, Engineering, and Medicine. She was co-chair of the U.S. National Academies' Committee on Embryonic Stem Cell Research Guidelines, co-chair of its Committee on Human Gene Editing, and recently completed service as co-chair of the Regenerative Medicine Forum, among other activities. At present, she is a member of the NAM Council and of the U.S. National Academies Board on Health Sciences Policy and Committee on Science Technology and Law. Professor Charo served on President Obama's transition team, focusing on the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), bioethics, stem cell policy, and women's reproductive health. She was on leave from 2009 to 2011 to serve as a senior policy advisor on emerging technology issues in the Office of the Commissioner at FDA. Her federal advisory committee service includes the 1994 NIH Human Embryo Research Panel and President Clinton's National Bioethics Advisory Commission (1996 to 2001).

Baruch Fischhoff, Ph.D., is the Howard Heinz University Professor in the Institute for Politics and Strategy and the Departments of Engineering and Public Policy at Carnegie Mellon University. A graduate of the Detroit Public Schools, he holds a B.S. in mathematics and psychology from Wayne State University and an M.A. and a Ph.D. in psychology from the Hebrew University of Jerusalem. He is a member of the U.S. National Academy of Sciences and the U.S. National Academy of Medicine. He is past president of the Society for Judgment and Decision Making and of the Society for Risk Analysis, and recipient of the latter's Distinguished Achievement Award. He was founding chair of the Food and Drug Administration Risk Communication Advisory Committee and recently chaired the U.S. National Academies of Sciences, Engineering, and Medicine's Committee on Behavioral and Social Science Research to Improve Intelligence Analysis for National Security and co-chaired the U.S. National Academies' Committee on Future Research Goals and Directions for Foundational Science in Cybersecurity and the U.S. National Academy of Sciences Sackler Colloquium on "The Science of Science Communication." He was a mem-

ber of the planning committee for both of the White House–requested symposia on gain-of-function research. He is a former member of the Eugene, Oregon Commission on the Rights of Women, the Department of Homeland Security’s Science and Technology Advisory Committee, the World Federation of Scientists Permanent Monitoring Panel on Terrorism, and the Environmental Protection Agency Science Advisory Board, where he chaired the Homeland Security Advisory Committee. He is a Fellow of the American Psychological Association, the Association for Psychological Science (previously the American Psychological Society), the Society of Experimental Psychologists, and the Society for Risk Analysis. He has co-authored or edited 11 books: *Acceptable Risk* (1981), *A Two-State Solution in the Middle East: Prospects and Possibilities* (1993), *Elicitation of Preferences* (2000), *Risk Communication: A Mental Models Approach* (2002), *Intelligence Analysis: Behavioral and Social Science Foundations* (2011), *Risk: A Very Short Introduction* (2011), *Communicating Risks and Benefits: An Evidence-Based Guide* (2011), *Judgment and Decision Making* (2011), *Risk Analysis and Human Behavior* (2011), *The Science of Science Communication* (2013), and *Counting Civilian Casualties* (2013).

Michele Garfinkel, Ph.D., is the manager of the EMBO Science Policy Programme where she is responsible for policy research focused on biotechnology and scientific publishing. The EMBO Science Policy Programme also addresses subjects of concern to scientists and policy makers, including research funding and responsible conduct of research. Until March 2011, she was a policy analyst at the J. Craig Venter Institute. Her research there focused on identifying emerging societal concerns associated with new discoveries in genomics and crafting options for policy interventions. She was a principal author on the 2007 report “Synthetic Genomics: Options for Governance,” which remains a foundational study in the field. She has continued to be engaged in efforts to assess the biosafety and biosecurity implications of advances in synthetic biology, as well as on research integrity. For example, she was active in the European discussions of gain-of-function research and spoke at the workshop on Assessing the Security Implications of Genome Editing, in which the U.S. National Academies of Sciences, Engineering, and Medicine was a partner. She also served as an expert to the Technical Expert Working Group on Genetic Sequence Data for the World Health Organization (WHO) Pandemic Influenza Preparedness Framework Advisory Group. Dr. Garfinkel holds a Ph.D. in microbiology from the University of Washington, Seattle; an M.A. in science, technology, and public policy from The George Washington University; and an A.B. in genetics from the University of California, Berkeley.

Alexander (Sasha) Kagansky, Ph.D., is a director of the Centre for Genomic and Regenerative Medicine, School of Biomedicine, Far Eastern Federal University in Vladivostok, Russia, where he also teaches as an associate professor. He is also an executive committee member of the Global Young Academy. Previously, in 2012–2017 he worked as a Chancellor’s Fellow at the Medical Research Council (MRC) Human Genetics Unit, MRC Institute of Genetics and Molecular Medicine (IGMM) at the University of Edinburgh, Scotland, and led research at the Synthetic Epigenetics Lab, Chromosomes and Gene Expression Section of the IGMM. In 2005–2012, he worked at the Wellcome Trust Centre for Cell Biology, University of Edinburgh, as a postdoctoral research associate and then as senior research associate. Research in his center is aimed at understanding the molecular basis of the cell fate and tissue transitions in the human organism, and at finding ways to control these transitions, which will be crucial for the future of molecular medicine. In his studies he combines genetics, synthetic biology, biochemistry, and proteomics. Apart from the research in the laboratory, Dr. Kagansky regularly organizes public engagement of science activities in different parts of the world, which results in new collaborations between scientists and artists. He and the Global Young Academy recently organized an interactive session on potential biosecurity concerns arising from genome editing in conjunction with the international workshop on Assessing the Security Implications of Genome Editing Technology in Hannover, Germany. He also served on the planning committee for the workshop. Dr. Kagansky is a member of the Young Academy of Scotland and Mason Institute for Medicine, Life Sciences and the Law. He received his Ph.D. in molecular biology in 2004 after spending 3 years at the U.S. National Institutes of Health. In 1998 he got his M.S. in biophysics from St. Petersburg State Polytechnical University in Russia.

Alemka Markotić, M.D., Ph.D., is the director of the University Hospital for Infectious Diseases (UHID) in Zagreb, Croatia. She is head of the Department for Research and head of the Clinical Department for Urinary Tract Infections. She is also a full professor at the Medical School, University of Rijeka and Catholic University of Zagreb, Croatia, and an associate member of the Croatian Academy of Sciences and Arts. She received her M.D. at the Medical School, University of Sarajevo, Bosnia and Herzegovina (1989), an MSc. in Medical Microbiology and Parasitology (1996), and a Ph.D. in Infectious Diseases (1999) from the University of Zagreb Medical School. Her specializations are in Clinical Immunology (1997) and Infectious Diseases (2007). Dr. Markotić’s research on zoonoses with special focus on hantaviruses has earned her seven national and nine international awards, including the Croatian Academy of Arts and Sciences

Annual Award for Medicine, Annual State Award for Medicine, and the European Society of Clinical Microbiology and Infectious Diseases Award for Excellence. She has published more than 100 peer-reviewed papers and delivered numerous presentations at national and international conferences. At UHID Dr. Markotić established the Centre for Emerging and Re-emerging Infectious Diseases and is responsible for managing the first Croatian Biosafety Level (BSL)-3 laboratory. She is trained and certified for work in BSL-3 facilities and received theoretical training in BSL-4 level work at the U.S. Army Medical Research Institute for Infectious Diseases, Frederick, Maryland. At the request of the European Commission and Chinese Ministry of Agriculture, Dr. Markotić designed, organized, and presented a Biosafety/Biosecurity Training Workshop in Beijing, China, in May 2009. Dr. Markotić also worked for several years at the Institute of Immunology, Zagreb, a research institute that produces vaccines and immunologic reagents, and served as Head of the Viral Vaccines and Interferon Quality Control Unit. Dr. Markotić also lectures at the medical schools of University of Zagreb, Rijeka, and at the University of Split Croatia, where she has a course on Bioterrorism and Biodefense for Forensic School graduate students. She is a member of the Council of the International Society for Hantaviruses, the Board for Allergy and Clinical Immunology, and the Board for Genomics at the Croatian Academy of Science and Arts. Since 2016 she has served as a member of the Homeland Security Council. She also is a member of several national and international societies in immunology and infectious diseases. She has previously served on the Croatian National Council for Science and the Committee of the Croatian Sciences Foundation and as Vice-President of the Scientific Council in the Scope of Biomedicine and Health.

M. Iqbal Parker, Ph.D., is a professor in the Department of Medical Biochemistry and Structural Biology at the University of Cape Town. Dr. Parker obtained his Ph.D. in biochemistry in 1979 and completed a postdoctoral stint with Dr. Gary Stein at the University of Florida in Gainesville. He is the founding Director of the Cape Town Component of the International Centre for Genetic Engineering and Biotechnology (2007–2016). Prior to accepting this position, he was Head of the Department of Medical Biochemistry and the Director of Research for the Health Science Faculty at the University of Cape Town. Professor Parker is a founding member of the Academy of Science of South Africa (ASSAf) and served as General Secretary (2000–2004) and Vice President (2010–2016). He is a fellow of The World Academy of Sciences and the African Academy of Sciences. He served on the international jury panel for the Loreai/United Nations Educational, Scientific and Cultural Organization (UNESCO) Awards for Women in Science (1997–2002) and is currently

a member of the International Scientific Advisory Committees of the UNESCO International Centre for Biotechnology in Nsukka, Nigeria, and the UNESCO Biotechnology Centre in Tripoli, Libya. He is a Peer Reference Group Member for the International Science Programmes funded by the Swedish International Development Cooperation Agency. He is a former President of the South African Society of Biochemistry and Molecular Biology and the former Secretary General and current treasurer of the Federation of African Societies of Biochemistry and Molecular Biology. He served on the Executive Committee of the International Union of Biochemistry and Molecular Biology as the chair of the Committee on Symposia, chair of the Wood/Whelan Travel Fellowships Committee, and chair of the Mid-Career fellowships Committee (2009 and 2015). In 2003 he was awarded the National Science and Technology Forum award for "Outstanding Contributions in Science, Engineering and Technology," in 2004 he was awarded the South African Society for Biochemistry and Molecular Biology Gold Medal for his contributions to biochemistry, and received the Oettle Medal in 2009 from the Cancer Association of South Africa for significant contributions to cancer research. He is the chair of the ASSAf Biosafety and Biosecurity Committee that in 2015 presented the South African Academy report entitled "The State of Biosafety and Biosecurity in South Africa," which was presented during a side event at the 2017 Meeting of States Parties of the Biological Weapons Convention in Geneva in December 2017. He is a member of the South African Biological Weapons Working Committee and has participated in a number of Inter-Academy Partnership international biosecurity activities, most recently the workshop on Assessing the Security Implications of Genome Editing.

Alejandra G. Suárez, Ph.D., is the Academic Director of the School of Chemistry, Facultad de Ciencias Bioquímicas y Farmacéuticas, and full professor, Department of Organic Chemistry, at the Universidad Nacional de Rosario in Argentina. She is also a research scientist (project director), Instituto de Química Rosario, CONICET (Argentine National Scientific Research Council). Her primary research and teaching interests are in organic synthesis, organometallic chemistry, green chemistry, and chemistry education. She received her Ph.D. in chemical sciences from the Universidad Nacional de Córdoba in Argentina and did postdoctoral work at the Ecole Normale Supérieure in Paris and the University of Oxford. She was a member of the Chemistry Scientific Advisory Commission from the Argentine National Scientific Research Council (2012–2013) and has received national and international awards for her research. In addition to her scientific work, she has been active in chemical security and disarmament. She was a member of the Scientific Advisory Board of the Organization for the Prohibition of Chemical Weapons (OPCW) from

2009 to 2015, serving as its vice-chair from 2012 to 2013 and chair from 2013 to 2015. During that time she served on Temporary Working Groups on Verification, the Convergence between Chemistry and Biology, and Education and Outreach in Science and Technology. She led the OPCW project that produced The Hague Ethical Guidelines, a set of principles to be used in establishing or evaluating codes of conduct for scientists. She also served as the primary academic lead for an innovative project to introduce issues related to chemical weapons and the responsible use of chemicals into the chemistry curriculum in Argentine universities in ways that employed active learning methods.

Herawati Sudoyo, M.D., Ph.D., is the Deputy Director of the Eijkman Institute for Molecular Biology in Jakarta, Indonesia, and a teaching staff member at the Faculty of Medicine, University of Indonesia. She is also an honorary Associate Professor from the Faculty of Medicine, University of Sydney, Australia, and a member of the Indonesian Academy of Sciences. She received an M.D. from the University of Indonesia and obtained her Ph.D. in biochemistry/molecular biology from Monash University, Melbourne, Australia. Dr. Sudoyo's work on human genome diversity and disease and expertise on the use of DNA markers led to the establishment of a DNA forensics laboratory to serve the need of scientific evidence in solving criminal cases. The forensic laboratory has become part of the international forensic network on child trafficking and wildlife trafficking. Her latest professional appointment is President of the Indonesian Biorisk Association, whose mission is to raise awareness and build expertise on biosafety and biosecurity in Indonesia. She is involved in the development of the Indonesian Code of Conduct on Biosecurity, and established a strong collaboration with the Royal Dutch Academy of Arts and Sciences. Dr. Sudoyo has been actively participating as a member of the Indonesian delegation for the United Nations (UN) Biological and Toxin Weapons Convention Meeting of Experts since 2006, ASEAN Regional Forum Workshops on biosecurity issues, and others organized by the National Science Advisory Board on Biosecurity, UN Interregional Crime and Justice Research Institute, UN Food and Agriculture Organization, and the World Health Organization. She has been a member of the Expert Panel of the National Commission for Zoonosis since 2012. Dr. Sudoyo is also a member of several international organizations, including the PAN Asian SNP Initiative, HUGO, A-IMBN, Asia-Pacific Biosafety Association, and others. She previously served as a member of the U.S. National Academies of Sciences, Engineering, and Medicine's Committee on Dual Use Issues in the Life Sciences: Outreach Activities in Indonesia.

Appendix D

Collaborating Organizations

National Academies of Sciences, Engineering, and Medicine

See Front Matter for description.

InterAcademy Partnership

The InterAcademy Partnership (IAP) is a global network of more than 130 national and regional academies of science and medicine. Under IAP, the member academies work together to support the special role of science in efforts to seek solutions to address the world's most challenging problems. In particular, IAP harnesses the expertise of the world's scientific, medical, and engineering leaders to advance sound policies, improve public health, promote excellence in science education, and achieve other critical development goals.

One of the areas in which IAP undertakes projects and programmes is biotechnology and biosecurity. IAP created a Biosecurity Working Group in 2004 to bring the scientific and international communities together to develop responses to dual use issues in the life sciences and promote responsible research practices. It also undertakes ad hoc and collaborative activities addressing dual use and biosecurity issues. See <http://www.interacademies.org>.

Croatian Academy of Sciences and Arts

The main tasks of the Academy have been defined in Article 3 of the Croatian Academy of Sciences and Arts Act as follows:

- The Academy promotes and organizes scientific research and encourages the application of the findings of this research, develops artistic and cultural activities, and is concerned with Croatian cultural heritage and its affirmation throughout the world;
- It publishes the results of scientific research and artistic creation; and
- It makes proposals and gives its opinion on the promotion of sciences and arts in the fields which are of special importance to the Republic of Croatia.

The Croatian Academy's scientific and artistic activities are carried out through its nine departments, as well as through its scientific councils and committees, and scientific and research units (institutes). The Croatian Academy of Sciences and Arts collaborates with other academies of sciences and arts, universities, scientific institutions, state bodies, and cultural and other institutions, as well as with individual scholars and artists from Croatia and abroad. See http://info.hazu.hr/en/about_academy/primary_tasks.

Croatian Society for Biosafety and Biosecurity

The Croatian Society for Biosafety and Biosecurity (CSBB) was launched in 2014 with the aim of introducing a strategically important society involved in national biosafety and biosecurity issues. It is conceived as a nonprofit organization with the main objective to provide a platform for addressing and resolving issues related to biosecurity and biosafety at national and international levels. In addition to doctors from different fields, primarily infectious diseases, microbiology, and epidemiology, and experts in public health, it assembles a multidisciplinary scientific, medical, and academic community, including the pharmaceutical sector, veterinarians, biologists, and forensic field specialists. CSBB understands the importance of connecting different scientific fields on the principles of the "One Health Initiative." The cooperation between different experts is organized through international projects, conferences, and various forms of training. Moreover, a very important role of the CSBB resides in the technical expertise regarding the design of containment

laboratories for dangerous infectious agents. This national society also brings together experts in the fields of regulatory affairs, national security, and other related professions with the main goal of improving national and international biosecurity and biosafety. See http://www.hdbib.hr/index_en.html.

Appendix E

Examples of Activities Across the Governance Landscape

This appendix provides examples of relevant governance activities assembled as background to inform the workshop discussions and is augmented by input from participants. The material provides a snapshot as of October 2018; it does not provide a comprehensive accounting of actors and activities. Special thanks to Tracy Kambara for assembling these materials and observations during her Christine Mirzayan Science & Technology Policy Graduate Fellowship at the U.S. National Academies of Sciences, Engineering, and Medicine (the National Academies) in spring 2018. We also wish to acknowledge contributions made by participants at a preliminary discussion held on May 18, 2018, at the U.S. National Academies, particularly to supplement information on the landscape of U.S. governance activities addressing dual use life sciences research.

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
Argentina	Education and outreach	Government	National Project on Education on the Responsible and Safe Use of Chemical Science and Technologies
Argentina	Education and outreach	Universidad Nacional de Rosario	The responsible use of chemistry
Australia	Education and outreach	University of New South Wales Australia (via FutureLearn)	Biosecurity and Bioterrorism: Public Health Dimensions–MOOC
Australia	National policy	Government	Weapons of Mass Destruction (Prevention of Proliferation) Act 1995
Australia	National policy	Government	National Health Security Act (2007) and National Health Security Regulations (2008) (both revised 2013); Security Sensitive Biological Agent Standards

Summary

A four-pronged approach for education about chemical dual use issues through a partnership between the Ministry of Education and the Ministry of Foreign Affairs: (1) network of universities, (2) train-the-trainer program, (3) virtual classroom online learning platform, and (4) outreach.

<http://cancilleria.gov.ar/en/en-proyecto-nacional-de-educacion>

A description of the initiative in English may be found in a report by the Advisory Board on Education and Outreach of the Organization for the Prohibition of Chemical Weapons (https://www.opcw.org/fileadmin/OPCW/ABEO/abeo-5-01_e.pdf, pp. 26–27).

Implements topics related to bioethics, professional responsibility, and issues of the CWC in the curricula for the degree in chemistry through curricular activities, elective courses, and complementary activities.

http://www.fbioyf.unr.edu.ar/alumnos/quim/licquimica_descarga.htm

Free 4-week online course that covers epidemiology/infectious disease, biosecurity, bioterrorism, and policy/regulatory/ethical concerns related to biosecurity and bioterrorism. Taught by David Heslop, M.D.; David Muscatello; and Raina MacIntyre.

<https://www.futurelearn.com/courses/biosecurity-terrorism>

Export control regulations.

<http://www.legislation.gov.au/Series/C2004A04891>

See description of outreach program in Chapter 2.

Created in response to a 2006 review of the Council of Australian Governments. Establishes the Security Sensitive Biological Agents (SSBA) regulatory scheme. Lists SSBAs into two tiers based on security risk and requires registration for facilities handling these agents. Authorizes the Office of Gene Technology Regulator to inspect all facilities on a regular basis (every 18–24 months depending on SSBA tier). Also includes routine monitoring via spot checks and “desktop” inspections (paper-based compliance checks). The government has also put together “Fact Sheets” to aid in awareness of the SSBA scheme. Fact Sheet 14 is about dual use.

<http://www.health.gov.au/ssba>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
Bulgaria	National policy	Government	Relevant national legislation
Canada	National policy	Government	Human Pathogens and Toxins Act (2009)
Canada	National policy	Government	Human Pathogens and Toxins Regulation (2015)
Canada	National policy	Government	Tri-Agency Framework: Responsible Conduct of Research (2011) and Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (2010)
China/Pakistan	Code	Government	Proposal for the development of a model code of conduct for biological scientists under the Biological Weapons Convention

Summary

Relevant national legislation: Bulgarian Criminal Code, Chapter 11, section I, “Crimes Committed in Generally Dangerous Manner or by the use of Generally Dangerous Means,” articles 337 and 339 (last amended SG No. 19/2014); Bulgarian Defence-Related Products and Dual-Use Items and Technologies Export Control Act (last amended SG No. 9/2014); Decree of the Bulgarian Council of Ministers No. 158 of July 24, 2012, on the adoption of a list of Defence-Related Products and a list of Dual-Use Items and Technologies subject to control at import; Order No. 4 from 14.10.2002 of the Ministry of Labor and Social Policy and the Ministry of Health on the protection of workers from risks related to exposure to biological agents at work (SG No. 105/08.11.2002); Instruction No. 5 from 19.11.2003 of the Ministry of Health on the work with causative agents of bacterial, fungal, and viral infections with a high medical and epidemic risk (SG No. 105/14.03.2004); and Genetically Modified Organisms Act.

Expanded government oversight of research on genetically altered human pathogens, gain-of-function research, and dual use.

Implements provisions in 2009 Act and has a biosecurity focus. Requires a license for laboratories working on human pathogens and toxins, security clearance for personnel, inspections, designation of biological safety officer at each institution, and the development of a “Plan for Administrative Oversight” at each institution.

http://laws-lois.justice.gc.ca/eng/AnnualStatutes/2009_24/

Mandates an internal ethics review process at each private research institution; only applies to publicly funded research taking place at a private institution.

First introduced in 2015, a draft code of conduct developed by the Center for Biosafety Research and Strategy at Tianjin University was submitted to the Eighth Review Conference in 2016. Work on the code continues, with an international workshop at Tianjin in June 2018, and discussions during the BWC Meetings of Experts in July 2018.

See, for example, <http://undocs.org/en/BWC/MSP/2018/MX.2/WP.9> and [https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/A023173F53FE3DADC12582E80044947A/\\$file/TJU-Weiwen-2018-08-10-Request-3.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/A023173F53FE3DADC12582E80044947A/$file/TJU-Weiwen-2018-08-10-Request-3.pdf).

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Croatia	National policy	Government	Relevant national legislation and policy
Croatia	Funder guidelines	Government	Croatian Sciences Foundation
Croatia	Professional association	Nongovernment	Croatian Society for Biosafety and Biosecurity
Cuba	Code	Government	Code of professional ethics for science workers in Cuba (2016, see also Annex II: Principles and ethics associated with biosecurity)

Summary

Law on GMOs established in 2018, Law on Homeland Security System in 2017, and National Security Strategy in 2017.

Requires applicants to provide information concerning ethics and dual use issues when submitting project proposals.

For further information, see Appendix D.

http://www.hdbib.hr/index_en.html

Introduced at the 2016 BWC, the code lays out ethical principles and rules (both aspirational and advisory). Annex II focuses on biosecurity issues and includes dual use: scientists must “always bear in mind the potential repercussions - possibly damaging - of their research and recognize that a clear individual conscience does not justify ignoring the possible misuse of their scientific endeavors.”

<https://documents-dds-ny.un.org/doc/UNDOC/GEN/G16/221/05/pdf/G1622105.pdf>

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Denmark	National policy	Government	Act on securing biological substances, delivery systems, and related materials. Act no. 474 of June 2008. Executive Order on securing specific biological substances, delivery systems, and related materials. EO no. 981 of 15 October 2009 with Updated Annex 1 to EO 2017 (under Related Materials section j)
Denmark	Code	Government	
Egypt	National policy	Government	
France	National policy	Government	Code de la recherche (Research Code)
France	National policy	Government	Code de la santé publique (Public Health Code)

Summary

Administered by the Centre for Biosecurity and Biopreparedness (CBB). CBB has a variety of means to secure dual use technology. Public and private laboratories that intend to work with controlled materials must fill an application for a license to do so. In the application, they must also assess if they have any dual use technology. CBB will check up on this during inspections. Inspections can also be carried out in institutions and companies without a license from CBB, but with research activities that suggest dual use technology potential. If inspections indicate that the companies conduct research that is deemed to have a misuse potential, the organization/company must apply for a license from CBB. Spot checks and screening of publications are also conducted on a regular basis.

If dual use technology is detected the company is categorized according to the risk potential and must either obtain a license to continue its research activities and/or receive mandatory guidance and advice from CBB. Violations could result in fines or imprisonment. CBB also has a large number of outreach and educational activities where dual use technology is addressed specifically. Teaching and awareness-raising activities are arranged for biosecurity officers, university life sciences students (all levels), and researchers. For more information regarding regulation of immaterial technology with dual use potential in Denmark visit <https://www.biosecurity.dk/689>.

CBB adheres to a Code of Biosecurity Ethics: <https://www.biosecurity.dk/504>.

Within the last 10 years, Egypt has restructured many of its government agencies to manage increased science and technology (S&T) capabilities: (1) created the Ministry of Higher Education and Scientific Research (HCST) to design research policies; (2) restructured the Academy of Scientific Research and Technology (ASRT) as an advisory board for assessment and evaluation of research and policy only, no longer a funding body; (3) created the Science and Technology Development Fund (STDF) as a new funding agency; and (4) created the Egyptian Network of Research Ethics Committees (ENREC), focusing on the protection of research subjects.

Authorizes the High Council for the Evaluation of Research and Higher Education (an independent administrative body) to evaluate research and research institutions.

<https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006071190>

Imposes regulations on genetic and biomedical research for the protection of human subjects.

<https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
France	National policy	Government	Code de l'environnement (Environment Code)
France	National advisory board	Government	La Conseil National Consultatif Pour La Biosecurite (CNCB)
Germany	National policy/ position paper	Government	Committee on Biological Agents (ABAS)/The Federal Institute for Occupational Safety and Health (BAuA); "Biosecurity from an occupational safety and health perspective" (Decision 36/2011 of the ABAS)
Germany	Code	Max Planck Society	Guidelines and rules on a responsible approach to freedom of research and research risks (Max Planck Society, 2010)

Summary

Regulations on GMOs.

<https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074220>

National Advisory Council for Biosecurity whose mission is to inform the public authorities, the scientific community, and the public on security issues, profits, and the risks posed by the progress of research in the life sciences. It is empowered to make a range of recommendations for the funding, conduct, and dissemination of dual use research, as well as to forecast trends. The Council has six members, half from government and half nominated by the French Academy of Sciences.

<http://www.sgdsn.gouv.fr/missions/lutter-contre-la-proliferation/le-conseil-national-consultatif-pour-la-biosecurite-cnbc>

The ABAS is the advisory body of the BAuA on the Biological Agents Ordinance. Its members are public and private employers, trade unions/employees, state authorities, statutory accident insurance institutions, and universities and science institutions.

The position paper states that biosecurity measures can be considered as an extension of a biosafety programme in the framework of a general security management concept, which may be necessary only in the context of targeted activities in the framework of protection levels 3 and 4 and when working with toxins.

Biosecurity questions are regulated according to their exactly defined objectives in the legal areas of occupational safety and health and infection protection as well as in the legal areas of genetic engineering legislation, and in the framework of the elimination of epizootic diseases and plant protection among others.

Generally, ABAS refers to a vast majority of laboratory biosecurity issues in Germany being covered by a historically evolved legal network. Occupational health/biosafety surveilled in a dual approach by both supervisory authorities and carriers of legal accident insurances or trade unions. Furthermore, guidelines have a nationwide legal binding character.

https://www.baua.de/DE/Aufgaben/Geschaefsfuehrung-von-Ausschuessen/ABAS/pdf/Biosecurity-EN.pdf?__blob=publicationFile&v=2

Establishes the process for inclusion of risk mitigation plans for research applications submitted to Max Planck for funding. Specifies that all other Codes of Conduct in Germany apply to Max Planck researchers as long as their provisions do not conflict.

<https://www.mpg.de/197392/researchFreedomRisks.pdf>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Germany	Code	Leibniz Association	Code of Conduct for Biosecurity for Facilities dealing with Biological Resources (Leibniz Association, 2012)
Germany	Code	BIO Deutschland	Position Paper by BIO Deutschland on the Topic of Biosecurity: The Dual-Use Dilemma (2008)
Germany	Code	The Society for Virology	DURC Commission

Summary

The Leibniz Association is a group of 91 research institutes. The code essentially adopts the Code of Conduct on Biosecurity for Biological Resource Centres (2012, European Consortium of Microbial Resources Centres). Focus is on minimizing biorisk and misuse of biological resources.

http://www.embarc.eu/deliverables/EMbaRC_D.NA1.3.2_D2.34_BiosecCoCfinal%20for%20ExecCommAug2012.pdf

BIO Deutschland = Biotechnology Industry Organisation. Adopted the DFG Code of Conduct for its 330 member companies.

Starts on page 38 of <https://www.jura.uni-freiburg.de/de/institute/ioeffr2/weiterfuehrendelinksdokumenteordner/dokumenteordner/2013-4.-quartal/codes-of-conduct-on-biosecurity.pdf>.

Provides opinions and recommendations. Homepage is being updated at time of publication.

https://www.g-f-v.org/kommission_durc and https://www.gfv-sub.webspace.rocks/DURC/durc_main.html

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
Germany	Code	Robert Koch Institute (and others)	Code of conduct for risk assessment and risk mitigation: "Dual use potential of life sciences research" (2013)
Germany	Policy research	University of Hamburg/The Carl Friedrich von Weizsäcker-Centre for Science and Peace Research (ZNF)	Interdisciplinary Research Group on the Analysis of Biological Risks (INFABRI), one project on "Governance of Dual Use Research of Concern"

Summary

The Robert Koch Institute (RKI) is the government's central scientific institution in the field of biomedicine and the national public health institute commissioned to protect and improve the health of the population. It is a federal institute within the portfolio of the Federal Ministry of Health.

The code of conduct, which is obligatory for employees of RKI, is a risk assessment and risk management tool. It provides the criteria for assessing the dual use potential of research projects and their results. Along with the code of conduct, awareness raising via training and seminars is planned for the future.

Other local codes of conduct:

Technische Universität Darmstadt: <https://www.intern.tu-darmstadt.de/gremien/ethikkommission/zivilklausel/zivilklausel.de.jsp>

Uni Marburg: https://www.uni-marburg.de/de/universitaet/administration/amtliche-mitteilungen/jahrgang2015/02_2015.pdf (German)

Fraunhofer Gesellschaft: Europe's largest application-oriented research organization puts emphasis on information, consulting, and sensitization and has established an export control system for all actions and activities, which centrally controls the topic of dual use under the inclusion of Fraunhofer Institutes and facilities.

<https://www.fraunhofer.de/de/ueber-fraunhofer/corporate-responsibility/forschung-und-entwicklung/ethik-und-wissenschaftsverantwortung.html>

All of the above listed in the table "Contact persons and committees in Germany responsible for ethics concerning security-relevant research" (see entry for Leopoldina and DFG below).

Publicly funded research group to assess the comparative risks of different biological threat scenarios and available response options. This includes one project on the governance of Dual Use Research of Concern.

<https://www.znf.uni-hamburg.de/forschung/infabri.html>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
Germany	Code	German Research Foundation (DFG)	Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins (DFG, 2013)
Germany	Policy	German Ethics Council	<i>Biosecurity—Freedom and Responsibility of Research</i> (2014, German Ethics Council report)
Germany	Code	Leopoldina and DFG	Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security Relevant Research (DFG and Leopoldina joint committee, 2014)

Summary

DFG = the self-governing organization for science and research in Germany, which receives the large majority of its funds from the federal government and the federal states being represented in all grants committees.

Establishes a procedure for reviewing research proposals with dual use: principal investigators (PIs) must address the presence of dual use in their research, then reviewers will assess and make recommendations before funding is approved.

http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2013/130313_verhaltenscodex_dual_use_en.pdf

Report was commissioned by the government in response to the gain-of-function controversy. Recommends legislation to regulate dual use research: (1) creation of dual use commission that approves dual use funding; (2) creation of legally binding regulations on dual use; and (3) development of a national biosecurity code of conduct for the scientific community. Also lists existing regulations not explicitly about dual use but relevant to biosecurity. A Joint Committee of Leopoldina and DFG (German Research Foundation) on the handling of security-relevant research was created in response, as an alternative to legislation.

<http://www.ethikrat.org/files/opinion-biosecurity.pdf>

Leopoldina = The “Deutsche Akademie der Naturforscher Leopoldina” (German National Academy of Sciences), which scientifically reviews and addresses key issues of prospective significance to society. Its findings are conveyed to policy makers and the public alike and are nationally and internationally advocated.

As part of the gain-of-function debate, DFG and the Leopoldina appointed a joint interdisciplinary and cross-institutional working group in Summer 2013 that was tasked with analyzing and discussing the complex relationship between freedom of research and research risks.

Its report describes balance between academic freedom and social responsibility and legal and ethical constraints on research. The report also lists recommendations for both individual scientists and research institutions on minimizing risk associated with dual use research.

https://www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Germany	N/A	Leopoldina and DFG	Joint Committee of Leopoldina and DFG (German Research Foundation) on the handling of security-relevant research and Contact persons and committees in Germany responsible for ethics concerning security-relevant research
Germany	Code	Leopoldina and DFG	Model Statutes for Committees for Ethics in Security-Relevant Research (Joint Committee of Leopoldina and DFG, 2016)
Indonesia	Code	Indonesian Academy of Sciences	Code of Conduct on Biosecurity

Summary

A private–public partnership committee that aims to implement recommendations from the publication listed above. This committee oversees the creation and guidance of Committees for Ethics in Security-Relevant Research (KEFs) at research institutions.

<https://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use>

For committees and contact persons, see <https://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use/list-of-committees>.

Provides guidance for setting up and operating Committees for Ethics in Security-Relevant Research and for ensuring uniformity across different institutions. First progress report of the committee was published in October 2016.

https://www.leopoldina.org/fileadmin/redaktion/Ueber_uns/Kooperationen/2016_Model_Statutes_Committee_on_Ethics_in_Security-Relevant_Research.pdf

A code of conduct created by the Indonesian Academy of Sciences, with support from the Royal Netherlands Academy of Arts and Sciences. Introduced in 2016 at the Academy's 25th anniversary and disseminated within the Indonesian research community.

<http://perpustakaan.depkes.go.id:8180/bitstream//123456789/4502/1/Pedoman%20Perilaku%20untuk%20Keamanan%20Hayati%20=%20Code%20of%20Conduct%20on%20Biosecurity%202014.pdf>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Israel	National policy	Government	Regulation of Research into Biological Disease Agents Act (2008)
Israel	National advisory board	Government	Council for the Regulation of Research in Biological Pathogens
Japan	Code	Science Council of Japan (government)	Code of Conduct for Scientists (Science Council of Japan, revised in 2013 to include dual use)
Japan	National policy	Government	Infectious Diseases Control Law (revised 2007)
Japan	National policy	Government	Domestic Animal Infectious Disease Control Law (amended 2011)
Jordan	National policy	Government	Jordan Biorisk Management Guidelines (Ministry of Health, 2016)

Summary

Created in response to a report by the Steering Committee on Issues in Biotechnological Research in an Age of Terrorism (COBRAT, 2008). Authorizes the Ministry of Health (MOH) to oversee research institutions that possess or conduct research on select agents; requires MOH authorization to work on select agents (licensing); requires institutional biosafety and biosecurity committees comprised of scientists, security experts, and safety personnel to supervise research; and establishes a council for biological disease agent research to advise MOH.

<https://www.health.gov.il/English/MinistryUnits/PH/Scientist/Pages/default.aspx>

Fifteen-member council with a mix of technical experts from government ministries and academics from the fields of microbiology, infectious diseases, or biotechnology, and advises the Ministry of Health on the implementation of the 2008 regulations.

<https://www.health.gov.il/Services/Committee/Pages/CommitteeList.aspx>

Ethics regarding dual use: "Recognizing the potential malicious use of their research products for destructive purposes against their will, scientists shall choose appropriate and socially acceptable media and manners for disclosing their research process and products." Dual use reviews are not currently included in funding decisions for health science grants by the Ministry of Health, Labour, and Welfare.

http://www.scj.go.jp/ja/scj/kihan/kihan.pamflet_en.pdf

Classifies pathogens into four groups based on risk levels, and imposes regulations surrounding possession, importation, and transport for each.

Authorizes Ministry of Agriculture, Forestry and Fisheries to issue permits for use or possession of livestock pathogens and requires outbreak prevention plans and inventory keeping.

Focuses on biosafety and risk management, not dual use or biosecurity. National Biorisk Management Policy is to be created in line with these guidelines.

<http://emphnet.net/wp-content/uploads/2016/08/Jordan-Biorisk-Management-Guideline.pdf>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Malaysia	Code	Government	Code of Conduct (STRIDE/Ministry of Defense, draft, 2015)
Malaysia	Education and outreach	Academy of Sciences Malaysia	Educational Module on Responsible Conduct of Research (RCR)—online Module
Malaysia	National policy	Government	Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline (2015, Ministry of Health)
Malaysia	National policy	Government	National Biosafety Act (2007)
Netherlands	Code	Royal Netherlands Academy of Arts and Sciences KNAW	Code of Conduct for Biosecurity (2008, Royal Netherlands Academy of Arts and Sciences KNAW)
Netherlands	National policy	Government	Ministry of Economic Affairs, Manual on Strategic Goods (2011)

Summary

Developed by STRIDE, in collaboration with the Ministry of Health. Draft incorporates feedback and guidance of academic and industry scientists, including Academy of Sciences Malaysia, that was collected from workshops held throughout Malaysia in 2015.

https://issuu.com/asmpub/docs/code_of_conduct_for_biosecurity_wor

The first publication in Malaysia outlining RCR practices, including a chapter on dual use issues, and based on active learning approaches.

https://issuu.com/asmpub/docs/rcr_module_readonly

Primarily a biosafety policy.

http://mkak.moh.gov.my/download/Biosafety_Policy_and_Guideline_2015.pdf

Establishes a National Biosafety Board to oversee biosafety and GMO research.

<http://www.utar.edu.my/osh/file/Biosafety%20Act%202007%20-%20Act%20678.pdf>

Developed at the request of the Dutch government after 2005 BWC discussions. Section 4.3 on Dual Use similar to U.S. NSABB definition of dual use. Reviewed in the wake of the gain-of-function controversy.

<https://knav.nl/en/news/publications/a-code-of-conduct-for-biosecurity>

Export control regulations. Lists dual use goods, although most are not related to life sciences. Includes microorganisms and toxins (does not specify).

www.hetInvloket.nl/txmpub/files/?p_file_id=2201306

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
Netherlands	National policy	Government	Ministerial Regulation on GMOs; Environmental Management Act; Establishment and Permits Decree
Netherlands		Biosecurity Office	Workshops, online modules, and resource collection
Singapore	National policy	Government	Biological Agents and Toxins Act (2006)
Singapore	National policy (effectively)	Bioethics Advisory Committee	Research Involving Human Subjects: Guidelines for IRBs (2004, Bioethics Advisory Committee report)
South Africa	National policy	Government	Non-Proliferation of Weapons of Mass Destruction Act (1993)

Summary

Regulations specifically for GMO research; must have a permit for “activities involving GMOs.”

The Biosecurity Office undertakes a variety of education and outreach activities, including workshops bringing together various stakeholders (universities, medical centers, industry, veterinarians, plant scientists, etc.). “Toolkits,” surveys that identify biosecurity strengths and weaknesses within an organization, are available on the website (<https://www.bureaubiosecurity.nl/Toolkit>). The Office also created a 5-minute movie on the “8 pillars of biosecurity” (https://www.bureaubiosecurity.nl/en/Information/Biosecurity_movie).

[https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/F4010F726D2F812CC1257EAB0056AD76/\\$file/Ppt.+2+Raising+biosecurity+awareness+among+professionals.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/F4010F726D2F812CC1257EAB0056AD76/$file/Ppt.+2+Raising+biosecurity+awareness+among+professionals.pdf)

Establishes a biosafety regulatory framework and regulates possession/use/transport of biological agents and toxins. Requires inventory control, permits, and Ministry of Health to certify research facilities on a regular basis.

<https://sso.agc.gov.sg/Act/BATA2005>

Established a comprehensive ethical review focused on Institutional Review Boards (IRBs). Although not in itself a legal document, the Ministry of Health requires medical practitioners to comply with the guidelines, and the Agency of Science Technology and Research (A*STAR), the main biomedical research funding agency, requires compliance for funding.

<http://www.bioethics-singapore.org/index/publications/reports/172-research-involving-human-subjects-guidelines-for-irbs.html>

Facilities working with select agents or equipment are required to register with the South African Council for the Non-Proliferation of WMDs (“Non-Proliferation Council”). The BW Working Committee is a subgroup of this Council, which advises on chemical and biological weapons and controls.

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
South Africa	National policy	Government	Health Act (2003): various regulations updating the act (2012)
South Africa	National policy	Government	Animal Diseases Act (1984)
South Africa	National policy	Government	Hazardous Substances Act (1973)
South Africa	Policy research	Academy of Science of South Africa	<i>The State of Biosafety and Biosecurity in South Africa</i>
South Africa	Policy research	Academy of Science of South Africa	<i>The State of Laboratory Biosafety and Biosecurity in the Southern African Development Community (SADC) Region</i>
Switzerland	Norms/principles	Swiss Academies of Arts and Sciences	<i>Misuse Potential and Biosecurity in Life Sciences Research: A Discussion Basis for Scientists on How to Address the Dual Use Dilemma of Biological Research</i>

Summary

Regulations for biological materials, possession/handling of pathogens, biosafety, and biomedical research.

Research guidelines and import/export permits.

Classifies substances and regulates use, sale, and production of certain pathogens.

The 2015 consensus report includes descriptions of national legislation related to biosecurity and biosafety, including those submitted to show compliance with UNSCR 1540.

<https://www.assaf.org.za/files/2017%20reports/The%20State%20of%20Biosafety%20%20Biosecurity%20Report%20FINAL.pdf>

Proceedings of a March 2018 regional conference, building on the consensus study cited above.

The proceedings may be found at <http://hdl.handle.net/20.500.11911/101>; photographs and presentations at https://drive.google.com/open?id=1daX0Jju3N4lJWm_IubeLPW9ia9kZLnmq.

Discussion document-based outcomes of three workshops with life scientists to establish principles that should be considered when doing science. Includes sections on awareness and assessing misuse potential.

http://swiss-academies.ch/en/dms/publikationen/12/report1203e_Biosecurity_Web.pdf

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Ukraine	Education and outreach	Palladin Institute of Biochemistry of the National Academy of Sciences of Ukraine	Project 633: Education and Awareness-Raising in Ukraine—workshops
United Kingdom	National policy	Government	Anti-Terrorism, Crime and Security Act (2001/2007)
United Kingdom	National policy	Government	Biological Security Strategy (2018)
United Kingdom	Funder guidelines	Public/private	Wellcome Trust/BBRC/MRC
United Kingdom	Education and outreach	Bradford Disarmament Research Centre (BDRC)	Dual Use Education Materials

Summary

Seminars and conferences about education related to biosafety and biosecurity. Established website to allow the community to stay connected (<http://bsseducation.com.ua>); translated and disseminated Bradford materials to Ukrainian university professors; developed Biosafety, Biosecurity, and Bioethics module based on United Kingdom's National Series.

http://www.bsseducation.com.ua/sites/default/files/Report%203%20Int_Met-Kyiv.pdf

Focuses on biosecurity: controlled access to pathogens and toxins; security clearance for personnel; and includes plant pathogens.

<https://www.legislation.gov.uk/ukpga/2001/24/contents>

Describes the UK government's response to biological risks under four pillars (Understand, Prevent, Detect, and Respond) and two cross-cutting themes (A Strong Science Base and The Role of Industry and Academia in Biological Security). It lays out a plan for a "cross-Government director-level governance board" to oversee implementation of the strategy.

<https://www.gov.uk/government/publications/biological-security-strategy>

Common statement on how the major public and private funders of life sciences research will manage potential dual use risks of research they support.

<https://wellcome.ac.uk/funding/managing-grant/managing-risks-research-misuse>

Education Module Resource (EMR): An online collection of lectures with notes, references, and videos. Covers BWC history and background, dual use issues, and governance issues. Available in English and Japanese.

National Series (NS): A resource collection; teaching guidelines and materials for facilitators, whether or not they are biosecurity subject-matter experts, which can be easily adapted for different countries.

Train-the-trainer programme (TTT): Online training; an online, 12-week course that was UK Master's accredited. Involves dual use scenarios and a sustainability component by asking students how they will incorporate EMRs into their curricula.

<https://www.brad.ac.uk/bioethics>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
United Kingdom	Education and outreach	Bradford Disarmament Research Centre (BDRC)	Biosecurity textbook and handbook of team-based learning (TBL) exercises
United Kingdom	Education and outreach	Bradford Disarmament Research Centre (BDRC)	Neuroscience
United States	Code	American Society for Microbiology (ASM)	Code of Ethics (2005)

Summary

Preventing Biological Threats: What You Can Do 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. *Biological Security Education Handbook: The Power of Team-Based Learning* has a number of exercises that relate to dual use issues and/or the responsibilities of scientists.

<https://www.brad.ac.uk/social-sciences/peace-studies/research/publications-and-projects/guide-to-biological-security-issues> (includes textbook, handbook, and information about the project)

[https://www.unog.ch/80256EE600585943/\(httpPages\)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument](https://www.unog.ch/80256EE600585943/(httpPages)/0A20E57D9F8424B8C12581D8007EC32E?OpenDocument) (includes translations in French and Russian for the textbook and French, Russian, and Arabic translations for the TBL handbook)

The Bradford Centre has also undertaken a variety of work related to dual use issues associated with neuroscience, including an earlier series of online materials similar to the EMR for the then UK Neuroscience Dual-Use Education Network, and more recent work with the Human Brain Project (HBP) under EC Horizon 2020. The latter includes a lecture on neuroscience and dual use as part of an HBP online course (<https://www.youtube.com/watch?v=Dc7Uwpdfwt8&list=PLvAS8zldX4Cg0nsIQ6gT39Ncl7Pnm8-XH&index=7>) and a workshop in 2018 in Sweden that featured a TBL Exercise on “Social, ethical and legal responsibilities of life sciences” that drew on the edited volume described above; the video of the exercise is available at <https://education.humanbrainproject.eu/web/1st-hbp-curriculum-ethics/workshop-media>.

More general information about the online courses of the HBP Education Programme may be found at <https://education.humanbrainproject.eu/web/hbp-curriculum-online-course/research-ethics-societal-impact> and about its work on Ethics and Society at <https://www.humanbrainproject.eu/en/social-ethical-reflective>.

Lists aspirational guiding principles as well as “rules of conduct,” which are more specific. Guiding principle 6 states “ASM members are obligated to discourage any use of microbiology contrary to the welfare of humankind, including the use of microbes as biological weapons. Bioterrorism violates the fundamental principles upon which the Society was founded and is abhorrent to the ASM and its members. ASM members will call to the attention of the public or the appropriate authorities misuses of microbiology or of information derived from microbiology.”

<https://www.asm.org/index.php/governance/code-of-ethics>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/Regulation/Code/Activity or Organizer, etc.
United States	Education and outreach	U.S. National Academies of Sciences, Engineering, and Medicine (the National Academies)	International Initiatives on Responsible Science
United States	Education and outreach	American Association for the Advancement of Science (AAAS)	International Engagement: Secure Science, Technology, and Research - BMENA Case Studies
United States	Education and outreach	Federation of American Scientists	Case Studies in Dual Use Biological Research and Case Studies in Agricultural Biosecurity
United States	Education and outreach	Sandia National Laboratories	Global Biorisk Management Curriculum—resource collection
United States	Education and outreach	Nuclear Threat Initiative (NTI)	NTI Education Tutorials—online modules

Summary

Train-the-trainer model of week-long (and shorter) workshops using active learning techniques to discuss responsible research practices (including dual use topics). Past workshops have been in the Middle East and North Africa and South/Southeast Asia. Many workshop participants become facilitators for future workshops.

<http://nas-sites.org/responsible-science>

AAAS designed a set of 10 practical training exercises for life scientists throughout the broader Middle East and North Africa (BMENA) region. The exercises are based on high quality, published life sciences research from the BMENA region and can be included in training courses, educational curricula, and awareness-raising programs.

<https://www.aaas.org/resources/international-engagement-secure-science-technology-and-research-bmena-case-studies>

The dual use case studies are intended to help define the issues associated with dual use research and security in the research laboratory. They include interviews with researchers whose legitimate scientific work could potentially be used for questionable or harmful endeavors, as well as a historical perspective on their research, bioterrorism, and research regulations. The materials include primary scientific research papers and discussion questions that are meant to raise awareness about the importance of responsible biological research. The agricultural biosecurity modules are intended to raise awareness about agricultural biosecurity issues in the United States and is targeted toward the educated public. These modules address two different aspects of agricultural biosecurity, the nexus of agricultural production and international security. They include interviews with experts, historical perspectives on agroterrorism, and regulations.

<https://fas.org/biosecurity/education/dualuse/index.html>; <https://fas.org/biosecurity/education/dualuse-agriculture>

Some of the basic documents are publicly available and some are proprietary.

http://ibctr.sandia.gov/human_capacity_development/hcd-gbrmc.html

Online tutorials developed in partnership with the James Martin Center for Nonproliferation Studies aimed at students, professionals, and the media. Topics include biological weapons, chemical weapons, and nuclear weapons. Tutorials are divided into modules with infographics, interactive maps, slides, and quizzes.

<http://tutorials.nti.org/table-of-contents>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
United States	Education and outreach	Johns Hopkins University (via Coursera)	Engineering Life: Synbio, Bioethics & Public Policy—MOOC
United States	Education and outreach	Georgia Institute of Technology	Sam Nunn Security Program (SNSP)
United States	National policy	Department of Health and Human Services	Science, Safety, and Security website
United States	National policy	Government	National Biodefense Strategy (2018)
United States	National policy	Government	Federal Select Agent Program (administered by CDC and USDA)

Summary

Six-week online course (not free) that covers GOF debate, synthetic biology, human health, and governance issues.

<https://www.coursera.org/learn/synbioethics>

Year-long program on intersection of science, technology, and security, with emphasis on emerging technologies and governance. Includes week-long immersion in Washington, DC, each spring.

<https://cistp.gatech.edu/programs/sam-nunn-security-program>

Consolidates links and descriptions of major dual use policies.

<https://www.phe.gov/s3/dualuse/Pages/default.aspx>

Describes the U.S. government's actions to address biological risks and respond to biothreats. An associated National Security Presidential Memorandum establishes a Biodefense Steering Committee chaired by the Secretary of the Department of Health and Human Services to coordinate implementation of the strategy.

<https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf>

The original Select Agent Program was created in 1996 under the Antiterrorism and Effective Death Penalty Act (P.L. 104-132) and then expanded by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (PATRIOT Act) (P.L. 107-56) and the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) of 2002. The program regulates the possession, use, and transfer of biological select agents and toxins (a list of human, plant, and animal pathogens and toxins that have the potential to pose significant threats); certain types of experiments require review and approval before they are carried out.

<https://www.selectagents.gov>

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
United States	National policy	Government	U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012)
United States	National policy	Government	U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014; effective September 2015)
United States	National advisory board	Government	National Science Advisory Board for Biosecurity (various reports and recommendations)

Summary

Federal agencies that conduct or fund potential Dual Use Research of Concern (DURC) must review research portfolios to screen for DURC, assess its risks and benefits, develop a risk mitigation plan in consultation with the research institution, and review annual progress reports for changes that may affect the risk assessment. If risk cannot be mitigated, federal agencies can ask researchers to voluntarily redact findings, classify the research, or terminate funding.

<https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

“The policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is the critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication.”

<https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

DURC Companion Guide: <https://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>

A set of case studies, *Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies*, “demonstrate the type of analysis that should be brought to bear during institutional reviews of DURC and highlight important administrative steps in the DURC review process.” They could also be used more broadly as an education tool about dual use issues.

<https://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf>

The NSABB is a federal advisory committee that addresses issues related to biosecurity and dual use research at the request of the U.S. government. The NSABB has up to 25 voting members with a broad range of expertise, as well as non-voting ex-officio members from 15 federal departments and agencies. The NSABB has produced reports and recommendations on a range of dual use and biosecurity issues, including proposed governance measures.

<https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
United States	National policy	Government	HHS Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA (2010)
United States	National policy	Government	Gain-of-function policies

United States	National policy	Government	Department of Homeland Security (DHS)
---------------	-----------------	------------	---------------------------------------

Summary

The primary goal of the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* is to minimize the risk that unauthorized individuals or individuals with malicious intent will obtain “toxins and agents of concern” through the use of nucleic acid synthesis technologies, and to simultaneously minimize any negative impacts on the conduct of research and business operations.

<https://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx>

White House funding pause and deliberative process (October 2014): <https://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf>.

NSABB final recommendations and related documents (May 2015 to May 2016): <https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb>.

Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (January 2017): <https://www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx>.

Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (December 2017); replaces 2013 guidance: <https://www.phe.gov/s3/dualuse/Documents/p3co.pdf>.

NIH announcement of lifting of funding pause (December 2017): <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research>.

DHS Directive 041-01; issued May 25, 2007. Compliance with, and Implementation of, Arms Control Agreements;

Also

Testimony describing DHS review of intramural research funded by or performed by DHS for DURC concerns or other BW/security concerns prior to publication or disclosure.

<https://www.dhs.gov/news/2012/04/26/written-testimony-science-and-technology-directorate-senate-committee-homeland>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
United States	National policy	Government	NBACC
United States	Self-governance	Journal publishers	Journal Editors and Authors Group "Statement on Scientific Publication and Security"
United States	Journal policies	Journal publisher	American Society for Microbiology journals
United States	Education and outreach	Government	Federal Experts Security Advisory Panel (FESAP)
United States	Outreach	Engineering Biology Research Consortium (EBRC)	Working group on security in engineering biology
Regional	Laboratory management	European Committee for Standardization (CEN)	Laboratory Biorisk Management, CEN Workshop Agreement (CWA) 15793 (2011)

Summary

Landon et al. 2015. Institutional Review of Dual Use Research of Concern to Support a Culture of Responsibility. *Journal of Bioterrorism and Biodefense* 2015, 6:1.

<http://dx.doi.org/10.4172/2157-2526.1000130>

Statement by prominent, primarily U.S. journal editors recognizing both value of scientific publication and potential risks of misuse. Urges journals to develop review processes and states that “on occasion an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified, or not be published. Scientific information is also communicated by other means: seminars, meetings, electronic posting, etc. Journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse.” Appeared simultaneously in *Science*, *Nature*, and *Proceedings of the National Academy of Sciences*.

<http://www.sciencemag.org/site/feature/data/security/statement.pdf>

The ASM policies are described in Casadevall et al. 2015. Dual-Use Research of Concern (DURC) Review at American Society for Microbiology Journals. *mBio* 6(4):e01236-15.

<http://mbio.asm.org/content/6/4/e01236-15.full%22>

FESAP Culture of Biosafety, Biosecurity, and Responsible Conduct (educational materials at <https://ebsaweb.eu/awareness-biosafety-and-biosecurity>; additional info at http://www.sciencediplomacy.org/files/perkins_et_al_biosafety_september_2017.pdf).

EBRC is a nonprofit membership organization focused on building partnerships between academia, industry, and government in precompetitive research in engineering biology. In addition to their focus on advancing research, they maintain a working group on security in engineering biology, including working toward advancing an improved culture of security within the research base.

www.ebrc.org

The agreement provides a management system to complement existing biosafety standards, such as those provided by the World Health Organization. Since CWAs have a set lifespan, there is a process under way to turn this into an ISO standard, which would apply internationally.

http://www.uab.cat/doc/CWA15793_2011

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
Regional	Funder guidelines	European Commission	Ethics self-assessment
Regional	Education and outreach	European Union (EU)—Non-proliferation Consortium	Online modules
Regional	Code	Europe—DIYbio community	DIYbio Code of Ethics from European Congress (draft, 2011)
Regional	Code	Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Italy, Mexico, and Spain	Code of Conduct for Scientists (2014)
Regional	Code	ALLEA—All European Academies	The European Code of Conduct for Research Integrity, Revised 2017

Summary

In its oversight of research under the Horizon 2020 program, the European Commission maintains a distinction between traditional dual use research and what it terms research that “involves materials, methods or technologies or generates knowledge that could be *misused for unethical purposes*” (emphasis added). “Although such research is usually carried out with benign intentions, it has the potential to harm humans, animals or the environment,” which corresponds to the concept developed in the Fink report. A researcher applying for funding addresses questions of whether his or her research has the potential for misuse as part of the mandatory ethics self-assessment that is part of the proposal process.

<https://erc.europa.eu/sites/default/files/document/file/EthicsSelfAssessmentStepByStep.pdf>

The EU Non-proliferation Consortium is a network of independent nonproliferation think tanks. In 2017, the consortium released a collection of 15 learning modules available online for free, including slides, videos, and quizzes. Module 3 is about biological weapons and covers research areas with misuse potential, background info on BWC, and bioweapons.

<https://nonproliferation-elearning.eu>

“In May 2011, individuals and delegates from regional groups of DIY biologists from across Europe came together at the London School of Economics BIOS Centre with the goal of generating an aspirational code of ethics for the emerging do-it-yourself biology movement. The congress was composed of participants from five countries, including Denmark, England, France, Germany, and Ireland.”

<https://diybio.org/codes/draft-diybio-code-of-ethics-from-european-congress>

Submitted as a draft document to the 2014 BWC that was meant to be a code “of general application” for life scientists. Discusses professional integrity (more aspirational), responsibility (includes improper use of information), and responsibility of scientific institutions.

[https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/A0E89AEE9BA5731AC1257DA4003BB8A1/\\$file/BWC_MSP_2014_WP.6.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/A0E89AEE9BA5731AC1257DA4003BB8A1/$file/BWC_MSP_2014_WP.6.pdf)

In addition to traditional elements of research integrity, the code stipulates that “Researchers recognise and manage potential harms and risks relating to their research.”

https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
International	Journal policies	Council of Science Editors (CSE)	<i>White Paper on Promoting Integrity in Scientific Journal Publications</i>
International	Certification	International Federation of Biosafety Associations (IFBA)	Professional Certification Program for Biorisk Management and Biosafety Professionals
International	Industry Initiative	International Gene Synthesis Consortium	Harmonized Screening Protocol (International Gene Synthesis Consortium, 2009, updated 2017)

Summary

The Council of Science Editors (CSE) is an international membership organization whose aim is to be “an authoritative resource on current and emerging issues in the communication of scientific information.” Since 2006 CSE has published a *White Paper on Promoting Integrity in Scientific Journal Publications*, which is periodically revised and, beginning in 2018, will be added to and updated on a rolling basis to keep pace with new information and best practices.

<https://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics>

“The IFBA has launched a new certification program for biorisk management and biosafety professionals worldwide. An IFBA certificant is an individual who has met the eligibility requirements and achieves acceptable performance levels on examinations. The IFBA certifies individuals at the ‘Level 1—Professional Certification’ and ‘Level 2—Specialist Professional Certification’ in a number of specializations and technical disciplines related to the field of biosafety, biosecurity and biorisk management. Certifications are valid for a period of 5 years and require ongoing maintenance demonstrating active upgrading of skills and participation in the profession.”

<http://www.internationalbiosafety.org/index.php/professional-certification/ifba-professional-certifications/about-the-program>

Voluntary screening of gene synthesis orders by member companies.

<https://genesynthesisconsortium.org/wp-content/uploads/IGSCHARmonizedProtocol11-21-17.pdf>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
International	Clearinghouse	UN Interregional Crime and Justice Research Institute (UNICRI)	International Network on Biotechnology (INB)
International	Education and outreach	EU CBRN Centres of Excellence	Project 18: International Network of universities and institutes for raising awareness on dual use concerns in biotechnology
International	Norms/principles	International Science Council (ISC)	<i>Freedom, Responsibility and Universality of Science</i> (2014)

Summary

The INB is a global network of academic and research institutions, nongovernmental and international organizations, and other stakeholders committed to advancing responsible and secure conduct in the life sciences. Network partners may be found in Asia, Europe, the MENA, and North and South America. In its clearinghouse role, the INB is developing a digital platform to view, download, upload, and share customizable and user-friendly teaching/training materials, which include technology briefs, case study videos, scenario-based exercises, and immersive learning (virtual reality laboratory tours). The INB also provides a sustainable platform for network partners to (co-)develop and share educational resources tailored to local needs.

[https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/DB56FEFFA3325E82C12582E4006A837A/\\$file/INB_Presentation_BWC+MXaug2018_9+Aug+2018.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/DB56FEFFA3325E82C12582E4006A837A/$file/INB_Presentation_BWC+MXaug2018_9+Aug+2018.pdf)

Two-year project (2013–2015): “To raise awareness of dual-use (peaceful use and misuse) concerns in bio-technology for academics, scientists, researchers, technicians and students, as well as to foster the sharing and transfer of best practices in biosafety and biosecurity.” Information about the implementation of the project is available on the website of the implementer, the Landau Network Centro Volta (see previous entry in this table). A similar project was carried out for chemistry (#42).

<http://www.cbrn-coe.eu/Projects/TabId/130/ArtMID/543/ArticleID/46/Project-18-International-Network-of-universities-and-institutes-for-raising-awareness-on-dual-use-concerns-in-bio-technology.aspx>

Published by the Committee on Freedom and Responsibility in the Conduct of Science (CFRS), this lists both the responsibilities and freedoms of scientists. “Given this potential for multiple-use, the demands on scientists to pay careful attention to their individual and communal responsibilities are higher than in many other areas of work. Scientists have an obligation to critically reflect upon how their expertise is used, particularly when asked to support decision-making and policy processes.”

<https://council.science/publications/freedom-responsibility-and-universality-of-science-2014>

NOTE: In 2018, the International Council for Science (ICSU) merged with the International Social Science Council and became the International Science Council (ISC). The work of the CFRS continues in the new organization.

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
International	Norms/principles	InterAcademy Partnership (IAP)	Statement on Biosecurity (2005)
International	Norms/principles	InterAcademy Partnership (IAP)	Statement on Synthetic Biology (2014)
International	Norms/principles	InterAcademy Partnership (IAP)	<i>Responsible Conduct in the Global Research Enterprise</i> (2012); <i>Doing Global Science</i> (2016)
International	Norms/principles	Organisation for the Prohibition of Chemical Weapons (OPCW)	The Hague Ethical Guidelines (2015)
International	Code	International Union of Biochemistry and Molecular Biology (IUBMB)	Code of Ethics (2005)

Summary

Describes five guiding principles for elements to be considered by organizations or other science bodies in drafting codes of conduct: awareness, safety and security, education and information, accountability, and oversight. Researchers should “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 endeavor.”

<http://www.interacademies.org/13912/IAP-Statement-on-Biosecurity>

IAP Statement on Realising Global Potential in Synthetic Biology: Scientific Opportunities and Good Governance. “Maintaining biosecurity brings challenges beyond those of biosafety: for biosecurity the core defence rests on the responsibility of the scientific community.”

http://www.interacademies.org/10878/Scientific_Opportunities_and_Good_Governance.aspx

Policy report and accompanying educational handbook prepared by an international committee provides globally applicable principles for responsible conduct of research, including biosecurity as part of “preventing the misuse of research and technology.”

<http://www.interacademies.org/19787/Responsible-Conduct-in-the-Global-Research-Enterprise>

Intended for guidance in creating ethical codes to support the Chemical Weapons Convention. Promotes sustainability, awareness and engagement, safety and security, oversight, education, ethics, accountability, and exchange of information. “Teachers, chemistry practitioners, and policymakers should be aware of the multiple uses of chemicals, specifically their use as chemical weapons or their precursors. They should promote the peaceful applications of chemicals and work to prevent any misuse of chemicals, scientific knowledge, tools and technologies....” The OPCW website also has a database of existing chemistry codes of conduct.

<http://www.interacademies.org/33345/Doing-Global-Science-A-Guide-to-Responsible-Conduct-in-the-Global-Research-Enterprise>

Created after the 2005 BWC discussions. Lists members’ obligation to the public, to other investigators, and to trainees. Similar to Code of Ethics by the American Society for Biochemistry and Molecular Biology (1998), but also includes “They will not engage knowingly in research that is intended for the production of agents of biological warfare or bioterrorism, nor promote such agents.”

<https://iubmb.org/about-iubmb/mission-code-of-ethics>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/ Activity or Organizer, etc.
International	Code	International Union of Microbiological Societies (IUMS)	Code of Ethics (2008)
International	Code	International Association of Synthetic Biology	Code of Conduct for Best Practices in Gene Synthesis (International Association of Synthetic Biology, 2009)
International	Code	UNESCO	Recommendation on Science and Scientific Researchers (revised 2017)
International	Code	iGEM (Synthetic Biology)	iGEM Safety Policy

Summary

Code resulted from discussions at the BWC in 2005. "IUMS is opposed to the misuse of microbiological knowledge, research and resources. In particular, IUMS also strives to promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons and therefore to protect the public's health and to promote world peace." Also encourages member societies to adopt codes.

<https://www.iums.org/index.php/code-of-ethics>

Voluntary screening of gene synthesis orders by member companies.

<http://op.bna.com.s3.amazonaws.com/hl.nsf/r%3FOpen%3Djaqo-7xqpnr>

Lists responsibilities and freedoms of individual researchers, institutions, and funding agencies. Researchers have a responsibility "to express themselves freely and openly on the ethical, human, scientific, social or ecological value of certain projects, and in those instances where the development of science and technology undermine human welfare, dignity and human rights or is 'dual use', they have the right to withdraw from those projects if their conscience so dictates and the right and responsibility to express themselves freely on and to report these concerns." Report on member states' progress in implementing the recommendations to occur every 4 years, starting in 2019. Annex contains a list of other conventions, recommendations, and initiatives (helpful resource for self-governance).

http://portal.unesco.org/en/ev.php-URL_ID=49455&URL_DO=DO_TOPIC&URL_SECTION=201.html

iGEM prohibits gene drives and has restrictions on antimicrobial resistance work, animal work, use of certain organisms, and a review process for genetic modifications. Compliance is necessary for entry into the competition. As an extra step, they have FBI presence at competitions to instill in students the potential connection between science and biosecurity issues (more education and outreach). See also "2017 iGEM safety and security insights" document.

<http://2017.igem.org/Safety/Policies>

continued

Country or Community	Type of Governance Activity	Organization	Name of Policy/ Regulation/ Code/Activity or Organizer, etc.
International	Funder guidelines	Gene Drive Funders and Supporters Consortium	Principles for Gene Drive Research

Summary

Published as Emerson et al., *Science* 358(6367):1135–1136; includes five guiding principles for sponsors and supporters of gene drive research and identifies signatories in the acknowledgement section. Does not address dual use but contains a potential model for such efforts.

<http://science.sciencemag.org/content/358/6367/1135>

Appendix F

Examples of Regional and International Forums, Organizations, or Bodies

This appendix provides examples of regional and international forums, organizations, or bodies assembled as background to inform the workshop discussions and augmented by input from participants. The material provides a snapshot as of October 2018; it does not provide a comprehensive accounting of all such groups that could potentially become involved in governance of dual use life sciences research.

	Forum, Organization, or Body	Category
1	Biological and Toxin Weapons Convention (BWC)	Disarmament conventions and forums
2	Chemical Weapons Convention (CWC)	Disarmament conventions and forums
3	UN Security Council Committee established pursuant to resolution 1540 (1540 Committee)	Disarmament conventions and forums
4	Interpol	Intergovernmental security organizations
5	UN International Crime and Justice Research Institute (UNICRI)	Intergovernmental security organizations

Summary

BWC provides a forum to discuss biosecurity, oversight of dual use research, codes of conduct, and other governance measures. Information about activities is provided during meetings by states parties and civil society. In addition, current EU funding supports education activities. The website includes additional information.

<https://www.unog.ch/bwc>

CWC provides a forum to discuss chemical weapons nonproliferation, including national implementation of the convention and cooperation on capacity building. The Organisation for the Prohibition of Chemical Weapons (OPCW) that implements the CWC provisions includes an Advisory Board on Education and Outreach and a Scientific Advisory Board that advises the Director-General on implications of relevant developments in science and technology.

<https://www.opcw.org/chemical-weapons-convention>

Resolution 1540 “obliges States, inter alia, to refrain from supporting by any means non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their means of delivery.” The Committee conducts national and regional outreach activities and national reports provide substantial information about relevant laws, regulations, and policies. UNSCR 2325, adopted in 2016, “Encourages States, as appropriate, to control access to intangible transfers of technology and to information that could be used for weapons of mass destruction and their means of delivery.”

<http://www.un.org/en/sc/1540>

Interpol facilitates international law enforcement cooperation. It includes a Bioterrorism Prevention Unit that undertakes activities such as Project Biosecure on “risk assessment of current biological threats related to global terrorism, technological vulnerabilities including dual-use research and the threats emanating from the dark net. The overarching objectives of Biosecure are to increase bioterrorism awareness, enhance coordination and cooperation on issues relating to communication and information sharing, media relations, threat/risk assessment, cybercrime, and interaction with Health.”

<https://www.interpol.int>; <https://www.interpol.int/Crime-areas/CBRNE/Bioterrorism/Project-Biosecure>

UNICRI’s mission is to advance crime prevention and control, including mitigating biological risks. Under its CBRN Risk Mitigation and Security Governance Programme, it administers EU grants for activities including education and capacity building and a Centers of Excellence program. It has also established a Knowledge Management System to share tools, exercises, and best practices and an International Network on Biotechnology to share educational resources on biosafety, biosecurity, and bioethics.

<http://www.unicri.it/topics/cbrn>; http://www.unicri.it/news/article/2017-07-13_International_Network_on_Biotechnology

continued

	Forum, Organization, or Body	Category
6	World Health Organization (WHO)	Additional intergovernmental conventions and organizations
7	World Organisation for Animal Health (OIE)	Additional intergovernmental conventions and organizations
8	UN Food and Agriculture Organization (FAO)	Additional intergovernmental conventions and organizations
9	UN Educational, Scientific and Cultural Organization (UNESCO)	Additional intergovernmental conventions and organizations
10	Convention on Biological Diversity (CBD)	Additional intergovernmental conventions and organizations
11	Organisation for Economic Co-operation and Development (OECD)	Additional intergovernmental organization

Summary

WHO's "primary role is to direct and coordinate international health within the United Nations system." In 2006 it published "Biorisk Management: Laboratory Biosecurity Guidance" and conducts training in this area; it is also a partner organization of the GHSA (see below). It has most recently become involved with dual use issues through the influenza gain-of-function controversy.

<http://www.who.int>

OIE is "responsible for improving animal health worldwide." Its current Strategic Plan (2016–2020) includes risk management and "Reduction of biological risks, whether they are of natural, accidental, or intentional origins." It is also a partner organization of the GHSA (see below) and held two international conferences on biosecurity in 2015 and 2017.

<http://www.oie.int>

FAO "leads international efforts to defeat hunger." It provides resources for biosafety and biological risk management in food and agriculture and is also a partner organization of the GHSA (see below).

<http://www.fao.org>

UNESCO "seeks to build peace through international cooperation in Education, the Sciences and Culture." It is a partner in the World Science Forum, held every 2 years addressing global science policy topics, and produces a World Science Report every 5 years. It is also home to the World Commission on Ethics in Science and Technology (COMEST), an advisory body and forum that considers the ethics of emerging technologies, among other areas.

<https://en.unesco.org>; <http://www.unesco.org/new/en/social-and-human-sciences/themes/comest>

CBD, along with associated protocols such as the Cartagena Protocol on Biosafety and Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, addresses issues such as movement of modified organisms and access and use of genetic resources. It also discusses biosafety and implications for ecosystems and biodiversity of advances in biotechnology such as synthetic biology.

<https://www.cbd.int>

OECD "work[s] with governments to understand what drives economic, social and environmental change." The Committee for Scientific and Technological Policy periodically holds ministerial meetings on science and technology policy; many OECD committees and working parties address relevant topics in biotechnology. In 2007 it published the "Best Practice Guidelines for Biological Resource Centers" that includes biosecurity; OECD has previously addressed dual use issues.

<http://www.oecd.org>

continued

	Forum, Organization, or Body	Category
12	Australia Group	Security policy coordination and action
13	Global Health Security Agenda (GHSa)	Security policy coordination and action
14	Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)	Security policy coordination and action
15	International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)	Security policy coordination and action
16	European Biosecurity Regulators Forum (EBRF)	Security policy coordination and action
17	Association of Southeast Asian Nations (ASEAN)	Regional organizations that address science, technology, and security issues

Summary

"The Australia Group (AG) is an informal forum of countries which, through the harmonisation of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons." It addresses dual use issues as part of intangible technology transfers.

<http://www.australiagroup.net>

GHSa is a "partnership of over 64 nations, international organizations, and non-governmental stakeholders to help build countries' capacity to help create a world safe and secure from infectious disease threats and elevate global health security as a national and global priority." Its Action Package Prevent 3: Biosafety and Biosecurity aims to promote biological risk management and biosafety and biosecurity measures, including training and outreach activities to "promote a shared culture of responsibility [and] reduce dual use risks."

<https://www.ghsagenda.org>; <https://www.ghsagenda.org/packages/p3-biosafety-biosecurity>

The GP "is an international forum for coordination of projects to prevent CBRN terrorism and proliferation." Its Biological Security Working Group includes five deliverables for 2012–2017. Aim #4 is to "Reinforce and strengthen biological non-proliferation principles, practices, and instruments," and Aim #5 is to "Reduce proliferation risks through the advancement and promotion of safe and responsible conduct in the biological sciences."

<http://www.gpwmd.com/bswg>

IEGBBR includes government regulatory officials in biosafety and biosecurity from 11 countries, with WHO, OIE, and the United Nations participating as nonmember observers. The group meets every 2 years to promote international cooperation, contribute to strengthening of biosafety and biosecurity oversight mechanisms, and support responses to emerging issues and threats posed by human and animal pathogens.

The EBRF includes members of government regulatory bodies from Denmark, France, The Netherlands, Sweden, Switzerland, and the United Kingdom. The group meets every 6 months to discuss topics in biosecurity and dual use. For example, in 2014 the group produced "Guidelines for the Implementation of Action B2." Action B2 of the EU CBRN Action Plan requires members to establish review procedures and a registry for secure substances and facilities working with such substances. The guide describes how member states can implement Action B2 and be in compliance with UNSCR 1540.

<http://www.ebrf.eu/about.html>; <http://www.ebrf.eu/documents.html>

ASEAN promotes regional economic growth, peace and stability, and collaboration. The association and member countries serve as regional and national conveners of workshops and courses addressing biosecurity and dual use.

<http://asean.org>

continued

	Forum, Organization, or Body	Category
18	European Union (EU) and European Commission (EC)	Regional organizations that address science, technology, and security issues
19	Organization of American States (OAS)	Regional organizations that may address science, technology, and security issues
20	African Union	Regional organizations that may address science, technology, and security issues
21	International Committee for the Red Cross (ICRC)	International nongovernmental organization
22	Global Research Council	International science forums
23	World Conferences on Research Integrity	International science forums
24	World Science Forum	International science forums

Summary

The EC serves as the “executive arm” of the European Union in developing strategy, implementing EU decisions and policies, and representing the EU in international bodies. EU funding supports projects on biosafety and biosecurity in member and partner countries; EU funding has also supported regional workshops and educational activities under the BWC.

https://europa.eu/european-union/index_en; https://ec.europa.eu/commission/index_en

OAS promotes regional political dialogue, collaboration, and other aims and incorporates four main pillars: “democracy, human rights, security, and development.” It has a program to support implementation of UNSCR 1540 including provision of technical assistance and capacity building to member states. It also holds ministerial meetings on topics such as education and science and technology.

<http://www.oas.org>

The African Union promotes regional cooperation and development, among other aims. The Union provides an opportunity for networks of expertise and discussions on topics such as biosafety and biosecurity.

<https://au.int>

ICRC works to ensure “humanitarian protection and assistance for victims of armed conflict and other situations of violence.” Its 2004 initiative on Biotechnology, Weapons, and Humanity introduced the ICRC’s concept of a “web of prevention” supporting biosecurity.

<https://www.icrc.org>; <https://www.icrc.org/eng/resources/documents/misc/5vdj7s.htm>

A virtual organization that annually convenes leaders of government science and engineering funding agencies from as many as 50 developed and developing countries to promote cooperation and collaboration and to address common problems.

<https://www.globalresearchcouncil.org/about>

The conferences are convened approximately every 2 to 3 years and focus on research integrity and responsible conduct of research.

<https://wcrif.org>

The Forum is convened every 2 years and address global science policy topics in cooperation with UNESCO, ICSU (now ISC), American Association for the Advancement of Science, and other global science partners.

<https://worldscienceforum.org>

continued

	Forum, Organization, or Body	Category
25	Science and Technology in Society Forum	International science forums
26	World Economic Forum	Additional international forums
27	InterAcademy Partnership (IAP)	International scientific organization/ union
28	International Science Council (ISC)	International scientific organizations
29	International Union of Biochemistry and Molecular Biology (IUBMB)	International scientific organizations

Summary

The Forum is convened annually in Japan and aims to provide an opportunity for dialogue on beneficial opportunities arising from developments in science and technology, as well as ethical, safety, and environmental issues.

<http://www.stsforum.org>

"The World Economic Forum is the International Organization for Public-Private Cooperation" and its activities take place at the intersection of three focus areas: "mastering the fourth industrial revolution," "solving the problems of the global commons," and "addressing global security issues." Under this last umbrella, it has convened discussions on biosecurity and biological risk reduction, including in the area of global health security.

<https://www.weforum.org>

IAP undertakes convening activities on topics related to biosecurity, dual use, and responsible conduct of science. It also produces statements and reports, such as "responsible Conduct in the Global Research Enterprise." In 2004, IAP convened a Biosecurity Working Group to serve as a focal point for activities in this area; membership includes national academies of Australia, China, Cuba, Egypt, India, Nigeria, Pakistan, Poland, Russia, the United Kingdom, and the United States.

<http://www.interacademies.org>

ISC "brings together 40 international scientific Unions and Associations and over 140 national and regional scientific organizations including Academies and Research Councils." (ISC formed in 2018 from the merger of the International Council for Science, ICSU, and the International Social Science Council, ISSC.) ISC Statute 7 notes that the free and responsible practice of science "requires responsibility at all levels to carry out and communicate scientific work with integrity, respect, fairness, trustworthiness, and transparency, recognising its benefits and possible harms." ISC's Committee on Freedom and Responsibility in the conduct of Science (CFRS) advises the governing board on issues in this area.

<https://council.science>; <https://council.science/topics/cfrs>

IUBMB "is devoted to promoting research and education in biochemistry and molecular biology throughout the world and gives particular attention to areas where the subject is still in its early development." Its code of ethics includes the obligation to "not engage knowingly in research that is intended for the production of agents of biological warfare or bioterrorism, nor promote such agents" and IUBMB has been a convening partner on several prior international forums on biosecurity.

<https://iubmb.org>

continued

	Forum, Organization, or Body	Category
30	International Union of Microbiological Societies (IUMS)	International scientific organizations
31	International Union for Pure and Applied Chemistry (IUPAC)	International scientific organizations
32	International Society for Stem Cell Research (ISSCR)	International scientific organizations

Summary

IUMS is a global organization that promotes research and cooperation in the microbiological sciences. In its Code of Ethics against Misuse of Scientific Knowledge, Research and Resources, "IUMS also strives to promote ethical conduct of research and training in the areas of biosecurity and biosafety so as to prevent use of microorganisms as biological weapons and therefore to protect the public's health and to promote world peace." It has been a convening partner on several prior international forums on biosecurity.

<https://www.iums.org>

IUPAC "is the global organization that provides objective scientific expertise and develops the essential tools for the application and communication of chemical knowledge for the benefit of humankind and the world." Through its project system it has convened conferences, developed educational materials, and undertaken other activities related to chemical and biological safety and security and responsible conduct of science. In partnership with OPCW it has convened a series of meetings on advances in science and technology to help inform CWC review conferences.

<https://iupac.org>

ISSCR is a "transnational, cross-disciplinary science-based organization dedicated to stem cell research." In addition to an annual meeting, awards, and other activities, it publishes guidelines addressing "cultural, political, legal, and ethical perspectives related to stem cell research and its translation to medicine," most recently updated in 2016 and available in several languages. These are not intended to address dual use issues but may serve as a potential model for a research community that wants to develop relevant practice, bioethics, and/or dual use guidelines for its field.

<http://www.isscr.org>
