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The Power of Team-Based Learning.**

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**Biological Security Education Handbook:**  
**The Power of Team-Based Learning**

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## **Credits**

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# Table of Contents

## *Chapter 1*

Introduction

## *Chapter 2*

Social, Ethical, and Legal Responsibilities of Life Scientists

## *Chapter 3*

Advances in Science and Technology, and the Biological and Toxin and Chemical Weapons

Conventions

## *Chapter 4*

Examining the Risk of Bioterrorism

## *Chapter 5*

Biosecurity in the Context of Natural Disease Outbreaks

## *Chapter 6*

The Biological and Toxin Weapons Convention and the Role of Scientists

## *Chapter 7*

The Web of Prevention

## *Chapter 8*

Dual Use and Responsible Conduct of Science

## *Chapter 9*

Convergence of Chemistry and Biology, Security Risks, and the Role of Industry

## *Chapter 10*

International and National Scientific Organisations, and Biological Security

## *Chapter 11*

Review of Scientific and Technological Developments and the Biological and Toxin

Weapons Convention

***Chapter 12***

Building Sustainable Partnerships between the Scientific and Law Enforcement Communities

***Chapter 13***

Interagency Communication and Biological Security

***Chapter 14***

National Implementation of Biosecurity in Denmark

***Chapter 15***

Sustainable Implementation of Biosecurity through National, Regional, and International Partnerships in Jordan

***Chapter 16***

National Implementation of Biosecurity and the Role of Scientists (1): A Case Study of South Africa

***Chapter 17***

National Implementation of Biosecurity and the Role of Scientists (1): A Case Study of Canada

***Chapter 18***

The Role of the Scientific Community in the Development and Strengthening of International Biosecurity Regulations

***Chapter 19***

Conclusion

# **Chapter 1: Introduction**

## **Combining Contents with Strategy: A Case for Team-Based Learning**

The term ‘biosecurity’ has been used in many different contexts for many different purposes. The present Handbook uses the concept of ‘biosecurity’ (or biological security) to mean successful minimising of the risks that the biological sciences will be deliberately or accidentally misused in a way which causes harm for humans, animals, plants or the environment, including through awareness and understanding of the risks. Biosecurity thus involves a complex and rapidly evolving set of issues that concern a broad range of stakeholders: policy makers, legislators, industry, academia, the security community, science educators, life science students and practitioners, and the general public.<sup>1</sup> Addressing those issues requires continuous cooperation among all concerned parties, that is, biosecurity awareness is a responsibility incumbent upon all.

The need for fostering awareness of biological security among those engaged in the life sciences has been widely acknowledged in various fora and, as a result, over the past few years a number of important initiatives have been carried out, designed to further education about the broader social, ethical, security and legal implications of cutting-edge biotechnology.<sup>2</sup> The chief objective of the present Handbook is to complement those efforts by combining teaching material on biological security with an active learning approach – Team-Based Learning (TBL) – to empower educators, students and practitioners as they begin to engage with biological security. The Handbook seeks to supplement the Guide ‘Preventing Biological Threats: What You Can Do’ by providing its users with tips and insights into how to implement its content in different educational settings. Part 5 of the Guide introduces the reader to the value of active learning in the context of biosecurity education and training. Chapter 20 in particular details the implementation of the TBL format at an interactive biosecurity seminar, and the results achieved by the seminar participants. Consequently, the Handbook aims to:

- i. Highlight the strengths of the TBL format in teaching biological security.
- ii. Provide practical guidance on how to organise, run, and facilitate TBL biosecurity seminars.
- iii. Offer sample sets of exercises based on the individual chapters of the Guide.



- iv. Explain how each set of exercises can be used for achieving specific learning objectives.

Each chapter of the Handbook introduces the reader to a key concept discussed in the respective chapter of the Guide, and elaborates on the specific learning objectives, which the TBL exercises are aimed at. Each set comprises Individual and Team Readiness Assurance Test questions, and Application Exercises in the form of multiple-choice problem-solving tasks and practical scenarios (see below).

A growing body of evidence suggests that the use of active learning approaches to teaching and training can significantly enhance the effectiveness of education programmes.<sup>3</sup> Part of the reason behind this trend is the fact that active learning strategies aid the learner in ‘unlocking’ their existing knowledge, and linking new subject matter to their established conceptual framework.<sup>4</sup> In other words, through case studies, scenarios, problem-solving games, role plays, and simulations – to name a few examples of active learning methods – learners are prompted to think critically, reflect, and develop understanding of unfamiliar concepts. Active learning approaches foster a learner-centred environment, where the learner rather than the instructor is at the centre of the activities taking place in the classroom.<sup>5</sup>

The Handbook focuses on a specific format of active learning instruction – Team Based Learning (TBL). This is a special form of collaborative learning which uses a specific sequence of individual work, group work, and immediate feedback to create a motivational framework, whereby the focus is shifted from conveying concepts by the instructor to the application of concepts by student teams.<sup>6</sup> TBL is an easy-to-replicate, user-friendly approach, that can be applied in many different educational settings at various stages of instruction, and for different purposes. It enables the instructor to cover new material in a way that engages learners as active participants, allowing them to take ownership of their own learning, and develop reflection and self-evaluation skills. Detailed Facilitation Notes on how to prepare for, hold, and assess TBL seminars/training sessions are provided in Appendix A.

The concept of combining TBL and education on biological security has been tried and tested on multiple occasions between 2012 and 2015. A series of TBL seminars, using the format either in its entirety, or elements thereof, was conducted in a range of locations with participants at different stages in their careers (see Table 1.1). The feedback received was generally positive.

**Table 1.1: Examples of TBL Seminars in Biological Security and Dual Use<sup>7</sup>**

<b>Title</b>	<b>Location</b>	<b>Date</b>	<b>Participation</b>
“Bioethics and Responsible Research”	Bradford, UK	November 2012	Bachelor- and Master-level students: life sciences, law, international relations, engineering – 30 participants
“Bioethics and Responsible Conduct of Life Science” – pre-conference seminar held at the 5 <sup>th</sup> Annual Conference of the Biosafety Association of Central Asia and the Caucasus	Tbilisi, Georgia	March 2014	Life science practitioners and researchers – 36 participants
“Training for Awareness-Raising on Dual-Use Concerns in Bio-Technology” – part of EU CBRN Centres of Excellence Project 18, “International Network of Universities and Institutes for Raising-Awareness on Dual Use Concerns in Biotechnology”	Zarqa, Jordan	March 2014	Bachelor- and Master-level life science and medical students – 22 participants
“Introduction into Biosafety, Biosecurity, and Dual-Use Concerns in Biotechnology” – part of EU CBRN Centres of Excellence Project 18	Kyiv, Ukraine	April 2014	Bachelor- and Master-level life science students – 79 participants
“Training of Specialists in the Field of Biological Risk Management and Dual-Use Biotechnology” – part of EU CBRN Centres of Excellence Project 18	Chisinau, Republic of Moldova	May 2014	Scientific researchers, laboratory specialists, and epidemiologists – 100 participants
“Team-Based Learning Seminar on Dual Use and Biosecurity” – EU CBRN Centres of Excellence Project 18	Rabat, Morocco	May 2014	PhD life science students – 39 participants
“Biosafety, Biosecurity, and Dual-Use Issues in Biotechnology” – part of Project P633, “Awareness-Raising and Education on Biosafety and Biosecurity in Ukraine”	Odessa, Ukraine	May 2015	Day 1: Bachelor- and Master-level life science students – 60 participants Day 2: Life science lecturers and educators – 30 participants
“Training Course on Bioethics” – part of an International Workshop, “Education and Awareness-Raising in Dual-Use Sciences”	Sarob, Tajikistan	June 2015	Life science researchers, medical doctors, government officials – 60 participants from Tajikistan, Russia, Kazakhstan, Kyrgyzstan, Pakistan,

			and Armenia
“Dual Use and Governance of Biotechnology” – part of EU/UNICRI Project B1, “Establishment of a Regional Training and Resource Centre in Biosafety, Biosecurity, and Laboratory Management in the South Caucasus”	Tbilisi, Georgia	August 2015	Life science professionals and researchers – 30 participants from Armenia, Azerbaijan, Georgia, and Turkey
“Responsible Research: Introduction to Dual-Use Biosecurity” – pre-conference seminar at the 58 <sup>th</sup> Annual Biological Safety Conference, American Biological Safety Association (ABSA)	Providence RI, USA	October 2015	Life science practitioners, biosafety officers, government officials – 28 participants

The TBL format comprises four essential elements:

- i. Teams
- ii. Accountability
- iii. Feedback
- iv. Assignment Design

**Teams** are typically formed of 5-7 learners. The instructor is responsible for the composition of the teams. The main goal in team-formation is to ensure a maximum degree of diversity. It is also important to avoid the formation of subgroups and coalitions, since previously established relationships within the team would inevitably impact on its dynamics. During each class/session, learners are required to work in the team, to which they have been assigned.<sup>8</sup>

**Accountability** is key, since the format requires learners to complete certain tasks in advance. Failure to do so automatically puts certain limits to the extent to which they can contribute to the discussion, and actively support their team during in-class activities. Since the format combines individual and team performance, learners quickly begin to appreciate the value of preparation. Moreover, it is the team, and not the instructor, that holds them accountable for the level of their engagement.

The **feedback** needs to be immediate and frequent. Participants need to know how they are progressing throughout the session. At the same time, they should also be given opportunities to feed in any queries/comments/uncertainties.

Last, but not least, the **assignment design** is critical, since it serves the dual function of promoting both learning and team development. To this end, each task in the TBL sets is

designed to prompt learners to solve problems, employing critical thinking, negotiation, decision-making, and argumentation skills.

All teams are expected to work on the same significant problem and make a specific choice. Reporting is done simultaneously, in order to ensure that teams do not influence one another's decision-making process.

The structure of a typical TBL session is illustrated in Table 1.2. Each component of the TBL sequence of activities has been mapped on the Bloom's Taxonomy of Learning Domains.<sup>9</sup>

**Table 1.2: TBL Sequence of Activities**

<b>TBL Sequence of Activities</b>	<b>Bloom's Taxonomy of Learning Domains</b>
<b>Pre-Reading Activity</b>	<b>Remembering</b>
<b>Individual Readiness Assurance Test (iRAT)</b>	<b>Understanding</b>
<b>Team-Readiness Assurance Test (tRAT)</b>	<b>Applying</b>
<b>Appeals and Short Feedback Session</b>	<b>Analysing</b>
<b>First Application Exercise</b>	<b>Evaluating</b>
<b>Second Application Exercise</b>	<b>Creating</b>

### **Getting Started**

The present section aims to offer step-by-step guidance on how to run a Team-Based Learning seminar, regardless of whether the format is used for a one-off event, or for a course to be delivered over an extended period of time.

## # Logistics

Since the format requires a good deal of facilitation, it is recommended that instructors are assisted by a co-facilitator. This applies particularly for large groups / classes, that exceed 30 people.

A typical training session has an estimated duration of about 2 hours. During this period, the full set of exercises allocated for any given chapter can be covered. Appendix B provides additional tips and guidance on how selected chapters of the Handbook could be combined to develop short courses and individual seminars, depending on the time available and the specific target audience. A suggested breakdown of session time, based on the TBL components is illustrated in Table 1.2.

**Table 1.2: Breakdown of TBL Activities**

<b>Activity</b>	<b>Duration</b>
Individual Readiness Assurance Test (iRAT)	~10 minutes
Team Readiness Assurance Test (tRAT)	~10 minutes
Appeal and Feedback	~20 minutes
First Application Exercise	~15 minutes
Second Application Exercise	~45 minutes
Debrief	~10 minutes

## # Preparation

At each session teams are presented with a seminar pack, containing the following items:

- i. Copies of the Individual Readiness Assurance Test (iRAT) – 1 for each team member
- ii. Copies of the Team Readiness Assurance Test (tRAT) –1 for each team member
- iii. Copies of the First Application Exercise – 1 for each team member
- iv. Copies of the Second Application Exercise – 1 for each team member
- v. Cards with letters A to H – 1 set per team
- vi. A card with a letter/number/symbol identifying each team – 1 per team
- vii. Flipchart, markers, post-it notes – 1 set per team

The packs are distributed as learners take their seats, within their respective teams. All materials need to be placed in the order of the TBL exercises, and only the designated materials need to be used for each single task.

### **# Pre-Readings**

The TBL exercises are designed in a way that requires the learners to be familiar with the corresponding chapter from the Guide. No additional background preparation is required. However, instructors are invited to supplement the essential reading with any other relevant information, in the form of articles, book chapters, reports, or videos of their choice. Additional material can be found in Appendix A of the Guide. Learners need to be made aware of the requirement to familiarise themselves with the pertinent Guide chapter, prior to the training session. It needs to be made clear that a failure to prepare for the seminar will prevent them from fully engaging in the activities taking place in the classroom, and benefiting from the learning experience.

### **# Individual Readiness Assurance Test (iRAT)**

This is a closed-book quiz conducted under exam conditions. Learners are required to complete the test individually, and no interaction among them is allowed. The test aims to assess learners' level of understanding of the main concepts, discussed in the relevant chapter of the Guide. In order to provide learners with immediate feedback, various online tools can be used. *Poll Everywhere*, for example, is an open-source online application, that allows the instructors to engage learners in an interactive manner, and obtain data quickly and easily.<sup>10</sup> Both the iRAT and tRAT can be set up via *Poll Everywhere*, and the learners can then submit their answers, using a free application on their smart phones, or an internet browser on their laptops. Instant feedback can be then collected and analysed. Alternatively, in the absence of internet connection, once the learners have completed the test, their papers are collected and marked, whilst the next exercise is carried out. The overall goal is to provide the learners with feedback, prior to the Appeal session.

### **# Team Readiness Assurance Test (tRAT)**

This is an identical test to the iRAT, which aims to assess the learners' understanding of the main concepts, discussed in the relevant chapter of the Guide, **as a team**. During this exercise, learners are allowed to interact with their fellow team members by completing the test together. This is a closed-book test, which once more precludes the learners from

consulting with books or other sources. To facilitate the provision of immediate feedback, scratch cards can be used, that allow learners to see straight away, if their answer is correct or not. This approach will also allow monitoring of how many attempts the team has needed to identify the correct answer. In the absence of scratch cards, specifically designed quiz sheets, whereby the answer for each multiple-choice question is given in the form of a sticker, can be used. At the end of the tRAT session, the results of the iRATs and tRATs are compared and announced.

### **#Appeal and Feedback Session**

During the Appeal, learners are granted the opportunity to debate both the questions and the answers of the iRATs/tRATs. Essentially, they are allowed to object to the phrasing of questions, and/or the correct answer provided, by offering a rationale for their position/choice. The instructor is expected to take their arguments seriously, and to engage in critical deliberation. Far from challenging the instructor's authority, the Appeal provides the learners with space to discuss in detail and analyse issues of interest, and to lay the groundwork of critical engagement and reflection, necessary for the application exercises, which are about to follow.

The purpose of the feedback session is to clarify any issues/queries that may have proved challenging. At this stage, it is recommended that the instructor takes some time to explain and focus on those questions, which the learners may have found difficult. Any additional, relevant information can also be presented here. Make sure that such 'lecture' interventions are kept brief.

### **# First Application Exercise**

This exercise generally takes the form of a multiple-choice problem-solving task, based on a corresponding chapter of the Guide. Each team is required to discuss and agree on a specific option, and to provide a rationale for their choice. All teams are required to announce their answer simultaneously, by raising the respective paper letter sign, found in their seminar pack. Each team needs to nominate a speaker who, when prompted, will the team's rationale. As the purpose of this activity is to encourage critical reflection, the focus is on the rationale that learners provide, and that has motivated them to choose a particular option, rather than on the choice *per se*. Please note that the questions are designed in such a way that no answer stands out as the single 'correct' one, and in some cases it may appear that more than one

answer is plausible. Instructors are invited to choose which answer they will consider ‘correct’, based on the information found in the respective chapter of the Guide.

### **# Second Application Exercise**

This exercise takes the form of a practical scenario, based on a corresponding chapter of the Guide. Learners are expected to read through the scenario, complete a hands-on task, and present their findings to the rest of the class. The purpose of the activity is to encourage learners not only to engage in a critical evaluation of the concepts they have been analysing, but also to demonstrate how they can apply them in a new, creative way. By doing so, learners are prompted to link the novel concepts to their existing experience, and to think about how they relate to their everyday practice. To maximise the effect of the learning experience, an element of competition among the teams can be added: e.g. the teams may be asked to peer-review, evaluate, and mark one another’s findings and performance.

### **# Debrief**

At this stage, learners may be asked to share their thoughts and reflections on the seminar: e.g. what they like / don’t like; what they have found of use / help / interest; whether they have found the format useful as a whole; and whether the experience has matched their expectations. Even if the format is used over an extended period of time (e.g. a semester), it is still a good idea to give the learners the space to voice their thoughts and reflections on the process, not least because this constitutes an essential part of the learning process.



## Chapter 2: Social, Ethical, and Legal Responsibilities of Life Scientists

### Key Learning Objectives

- i. Develop understanding of the novel security concerns arising from the advancement of the life sciences;
- ii. Understand the broader social, ethical, and legal responsibilities of life scientists;
- iii. Develop an appreciation of what scientists can do, in order to minimise the potential risks of misuse of their work.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information provided in Chapter 2, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

#### 1. Which statement about gain-of-function experiments is FALSE?

- a) There are strict international guidelines on how information about such experiments involving influenza has to be conducted and communicated.
- b) Such experiments are generally daily practice in the modern life sciences, and are not, in themselves, a cause for concern.
- c) Studies that seek to enhance the biological properties of biological agents, such as virulence and transmissibility, are examples of gain-of-function experiments.
- d) The creation of mammalian-transmissible H5N1 virus in 2011 constituted a gain-of-function experiment.

#### 2. Which characteristic does NOT apply to the H5N1 study, described in Chapter 2?

- a) It involved enhancing the transmissibility of a pathogen.
- b) It sought to alter the host range of a pathogen.
- c) It sought to make the virus airborne.
- d) It sought to enhance the pathogen's resistance to therapeutics.

**3. Based on the information provided in Chapter 2, the H5N1 controversy has demonstrated that**

- a) the majority of life scientists are well aware of biosecurity issues and their associated ethical and social responsibilities.
- b) it is possible to limit the flow of sensitive scientific information through appropriate governance arrangement, without infringing academic freedom.
- c) there is a need for a dialogue and a closer collaboration between life scientists and the security community, as far as biosecurity issues are concerned.
- d) the World Health Organization (WHO) is the ideal international agency, that should be tasked with the oversight of dual-use research.

**4. In January 2012, influenza researchers called for a temporary moratorium on all work involving H5N1, in response to**

- a) the recommendation of the National Science Advisory Board for Biosecurity (NASBB) that the studies needed to be published in a redacted form.
- b) the presentation given by the Rotterdam-based virologist, Ron Fouchier, in Malta on the potential for enhancing the virus' transmissibility.
- c) the publication of the "US Government Policy for Institutional Oversight on Life Science Dual-Use Research of Concern".
- d) the decision of the Dutch Government to apply export control legislation before Ron Fouchier's study could be published.

**5. Which statement is FALSE, based on Chapter 2?**

- a) The H5N1 debate commenced only after the studies were submitted for publication.
- b) The young scientists, who carried out the H5N1 studies, were not in the least surprised that their work attracted so much media and public attention.
- c) Most of the gain-of-function debate has subsequently shifted from biosecurity to biosafety issues.
- d) Some scientists are convinced that certain types of experiments may deserve to be declared unethical and morally forbidden.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- **You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice, or the points you considered when reaching a decision.**
- **You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.**

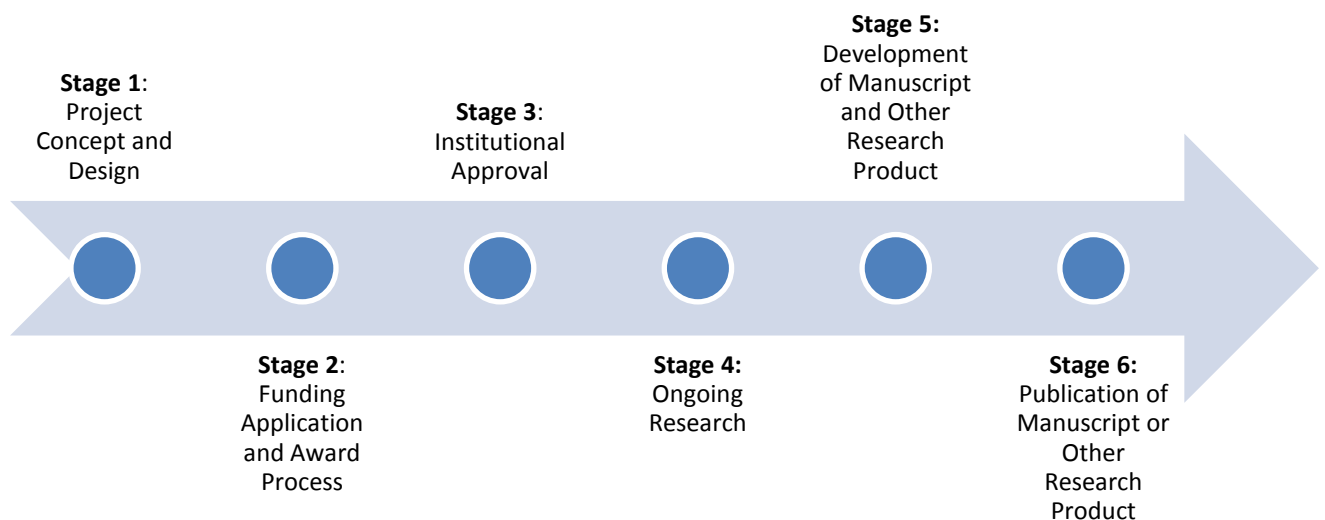
Based on the H5N1 controversy described in Chapter 2, identify which of the following stakeholders bears the chief burden of responsibility for the prolonged debate?

- A. The media who spread panic following the initial report on the findings presented by Ron Fouchier at the conference in Malta in September 2011;
- B. The funding agencies who should have demanded that the applicants submit a detailed risk-benefit analysis of the proposed studies related to biosecurity;
- C. The local institutional biosafety committees that should have insisted that scientists conduct thorough risk assessments with regard to biosecurity prior to, during and after the experiments;
- D. The scientists who should have ensured that measures were in place to address any potential biosecurity concerns likely to arise from the experiments, before submitting their funding proposals;
- E. The National Science Advisory Board for Biosecurity (NSABB) who should have allowed the publication of the manuscripts after having reviewed them in December 2011;
- F. The security community who should have developed guidelines for what kind of life science research should be subject to restrictions in terms of publication;
- G. The editorial boards of *Science* and *Nature* who should have published the papers without consulting the US Government and the NSABB;
- H. The US Government who should have classified the manuscripts when the editorial boards of *Science* and *Nature* consulted them.

## Second Application Exercise

### Instructions

- As noted in Chapter 2, scientists have broader responsibilities to society to ensure that their work does not pose unnecessary risks.
- Figure 1<sup>1</sup> below presents a timeline with the different stages of a research process – from the conceptual phase of the research to its final publication. For each stage identify the responsibilities of the life scientists conducting the research with regard to biosecurity, and suggest at least one action that could be taken to address any potential biosecurity concerns.



### Stage 1

Responsibilities:

Suggested Action(s):

### Stage 2

Responsibilities:

Suggested Action(s):

### Stage 3

Responsibilities:

Suggested Action(s):

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<sup>1</sup> Figure 1 is modelled on Figure 2 in NSABB, *Proposed Framework for Oversight of Dual-Use Life Science Research*, 2007, p.26.

**Stage 4**

Responsibilities:

Suggested Action(s):

**Stage 5**

Responsibilities:

Suggested Action(s):

**Stage 6**

Responsibilities:

Suggested Action(s):

## **Chapter 3: Advances in Science and Technology, and the Biological and Toxin and Chemical Weapons Conventions**

### **Key Learning Objectives**

- i. Understand that scientific and technological advances in the life sciences have been exploited for hostile purposes;
- ii. Understand that scientists have a role to play in safeguarding their work against the risk of hostile misuse;
- iii. Develop an appreciation of the ways in which scientists can help minimise the biological security risks arising from their work.

### **Individual/Team Readiness Assurance Test**

#### **Instructions**

- **Based on the information provided in Chapter 3, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

#### **1. Based on the information provided in Chapter 3, which statement BEST describes the state of microbiology in the late 19<sup>th</sup> century?**

- a) Scientists had begun to understand the relationship of specific microorganisms to specific diseases.
- b) The theory of spontaneous generation was reinforced and further developed.
- c) It was possible to determine the genetic structure of bacteria and viruses.
- d) The methods of action of pathogenic microorganisms were yet to be established.

#### **2. During the First World War**

- a) biological weapons were used both against animals and humans.
- b) Germany was the only country that deployed biological weapons.
- c) the use of poisonous weapons was allowed only as a retaliation measure.
- d) the use of biological weapons was prohibited.

**3. Which of the following statements is FALSE, according to Chapter 3?**

- a) Japan used biological weapons against the Chinese in the Second World War.
- b) A number of major states developed biological weapons in the years between the two world wars.
- c) The ethical concerns of scientists in the laboratory were a key factor when decisions about the use of biological weapons had to be made.
- d) The use of biological weapons was already banned when the Biological and Toxin Weapons Convention (BTWC) was negotiated.

**4. The history of the Soviet bioweapons programme demonstrates**

- a) the lack of interest of state officials in using novel scientific advances for military purposes.
- b) the challenges of setting up a secret system for the development of biological weapons.
- c) it is not possible to run such a programme for a long time without being caught.
- d) the crucial role that senior scientists played in its development.

**5. When assessing the development of third generation biological agents, it is possible to conclude that**

- a) its hostile misuse is unlikely.
- b) it has contributed to increasing the bioweapons threat spectrum.
- c) the dual use issues it raises are properly governed by the existing policy arrangements and mechanisms.
- d) scientists can do little to prevent its misapplication for malevolent purposes.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 3, which was the main factor in the use of the life sciences to develop offensive biological weapons programmes during the 20<sup>th</sup> century?

- A. The lack of international agreements prohibiting the use of biological weapons;
- B. The lack of international agreements prohibiting the development of biological weapons;
- C. The unquestioned effectiveness of biological weapons;
- D. The need for effective retaliation in case of first use by a state's enemy;
- E. The willingness of life scientists to take part in biological weapons programmes as part of their patriotic duty;
- F. The readiness of scientists to exploit the state's interest in biological weapons and thus attract additional research funding;
- G. The fact that other areas of science (e.g. physics and chemistry) had already been widely deployed for offensive purposes and biology was in no way different;
- H. The conviction that wars have no rules and any kind of weapon can be used.



## Second Application Exercise

### Instructions

- **Chapter 3 illustrates the involvement of life scientists in the campaign against biological weapons.**
- **Read the passage below and outline what action you, as a team of scientists, could take to address the situation described in the scenario. You need to provide a justification for your answer.**

Biological control (“biocontrol”) refers to the development and deployment of naturally occurring pathogens and insects for the protection of crops from disease caused by pathogenic agents and disease caused or transmitted by insect vectors. The technique is targeted against noxious organisms in the context of agriculture, such as weeds. It is developed and deployed for peaceful purposes with the consent of farmers and local authorities.

As a team of scientists working on the development of novel “biocontrol” agents, you come across a fungus that attacks coca plants – the plants used for the production of cocaine. After you have published your research, you discover that the military in your country have used your data to develop a method for the mass production of the fungus, and have used it against coca plantations in the territory of a neighbouring country, as a means of curtailing the production and spread of illicit drugs. The operation has been conducted without the consent of the victim country’s government. Moreover, you also begin to come across reports about the deleterious effects that the use of the fungus has on the environment, the soil, and on human health. You feel that you have a moral responsibility to take an action. What would that be?

### **Guiding Tips:**

- What would motivate you to feel responsible?
- How would you verify the information you have encountered?
- Who would you contact and what arguments would you use to build your case?
- What strategy would you use to ensure that your concerns are shared with as many people as possible and that they are effectively communicated to any relevant parties?
- What mechanisms would you use to raise awareness of the problem and encourage others to take action?
- How would you try to reach out to scientists who are sceptical about the likelihood that your campaign will be successful?

## Chapter 4: Examining the Risk of Bioterrorism

### Key Learning Objectives

- i. Understand the risk of bioterrorism in the context of the ongoing progress of the life sciences;
- ii. Develop an appreciation of the need for scientists to be aware of the risk, posed by bioterrorism;
- iii. Understand the ways in which scientists can play a role in safeguarding their work against misapplication for nefarious purposes.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information provided in Chapter 4, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

#### 1. What is the commonly accepted difference between 'bioterrorism' and 'biocrime'?

- a) The level of skill required for their perpetration.
- b) The type of weapons used.
- c) The kind of motivations that underpin them.
- d) The number of perpetrators involved.

#### 2. According to Chapter 4, a bioterrorist attack

- a) always requires the development of sophisticated bioweapons.
- b) is by definition a mass casualty attack.
- c) needs to be deadly, in order to be effective.
- d) is likely to have a significant psychological impact.

**3. Which statement about the ‘Amerithrax’ is FALSE?**

- a) It was the first case when the causative agent of anthrax was used for the purposes of bioterrorism.
- b) It required significant response and decontamination efforts amounting to over 320 million dollars.
- c) It drew attention to the ‘insider threat’.
- d) Initial speculations pointed toward Al-Qaeda as the primary perpetrator.

**4. Tacit knowledge is**

- a) easily codified.
- b) difficult to transfer.
- c) a minor factor in the development of biological weapons.
- d) not required in synthetic biology.

**5. Which statement BEST characterises the risk of bioterrorism, as presented in Chapter 4?**

- a) Given its historical record, bioterrorism appears unattractive.
- b) Given the advances in science and technology, committing a bioterrorist attack is relatively easy.
- c) A mass casualty bioterrorist attack in near future is both likely and possible.
- d) Increasing access to materials and proliferation of expertise could raise the risk of small-scale bioterrorism attacks.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- **You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice, or the points you considered when reaching a decision.**
- **You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.**

Based on the information provided in Chapter 4, which one of the following options best summarises the potential threat posed by bioterrorism:

- A. The threat is exaggerated; there is limited potential for the life sciences to be misused by non-state actors;
- B. The development /acquisition of even a very crude and simple biological weapon is very difficult and its effectiveness is not guaranteed;
- C. The tacit knowledge barrier means that would-be bioterrorists would always face obstacles to using novel technologies for hostile purposes, regardless of how much the technology evolves;
- D. While a bioterrorist attack involving high technology may be unlikely at this stage, the risk of a low-cost attack involving a crude weapon is real and requires that countermeasures are taken;
- E. The potential sources of a bioterrorist attack are known and clear, so it is easy to predict and assess the risk of who may choose to use pathogens and/or toxins for hostile purposes and under what circumstance;
- F. The scientists working in high-containment laboratories with access to dangerous pathogens pose by far the biggest bioterrorist threat;
- G. Synthetic biology poses by far the biggest bioterrorist threat, as it allows would-be bioterrorists to develop biological weapons fast, cheaply and in the absence of sophisticated equipment;
- H. Novel technologies can be easily exploited for bioterrorist purposes, even by individuals with no scientific expertise.

## Second Application Exercise

### Instructions

- **Chapter 4 gives an overview of the potential threat posed by bioterrorism and offers examples of past bioterrorist attacks, including the anthrax letters attack of 2001.**
- **While not a mass-casualty attack, the anthrax letters attack caused tremendous panic and widespread fear, and resulted in significant decontamination costs and tens of thousands people being given antibiotics.**
- **Read the scenario, complete the task and report to the class.**

Your team forms an institutional biosafety committee within a high-containment research facility, where work on dangerous pathogens, such as the causative agents of anthrax, plague, and Q fever, is carried out. In light of the anthrax letters attack, you have been tasked with reviewing the internal biosecurity policy to ensure that appropriate rules and procedures are in place with regard to the risk of bioterrorism. Suggest at least **three** measures that could help enhance biosecurity within the facility and prevent the potential hostile misuse of the pathogens hosted there. Think about how you would promote the new rules among the life scientists working at the facility.

### **Guiding Tips:**

- What are the potential biosecurity challenges that may arise in a high-containment facility?
- How can the 'insider threat' be addressed?
- How would you ensure that the measures you propose do not have a negative impact on the research work performed at the facility?
- What strategy would you use to promulgate the new policy among your colleagues?
- How would you ensure compliance with the new rules?

## **Chapter 5: Biosecurity in the Context of Natural Disease Outbreaks**

### **Key Learning Objectives**

- i. Understand the potential biological security threats, arising from natural disease outbreaks.
- ii. Understand how such threats can be addressed.
- iii. Develop an appreciation both of the potential biological security threats, arising from natural disease outbreaks, and of the role that the scientific community can play in preventing such threats.

### **Individual/Team Readiness Assurance Test**

#### **Instructions**

- **Based on the information provided in Chapter 5, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

**1. Which of the following statements about disease outbreaks is FALSE, according to Chapter 5?**

- a) They are characterised by an excess of disease cases, compared to what would normally be expected in a certain area/period.
- b) They can have a global reach through air travel and trade.
- c) Their number has increased significantly over the past 60 years.
- d) Most of them have been caused by agents of bioterrorism concern.

**2. According to Chapter 5, the potential biosecurity threat arising from a naturally-occurring disease outbreak**

- a) is exaggerated, as no group/individual has ever attempted to acquire biological agents during a disease outbreak.
- b) is heightened by the possibility that people with legitimate access to the designated facilities/samples could exploit that access for illicit activity.
- c) is high, as biological agents are easy to weaponise, once they are acquired.
- d) is high, because isolating an agent in its natural environment does not require significant technical knowledge.

**3. The case study of the 2014/2015 Ebola outbreak in West Africa, as presented in Chapter 5, shows that**

- a) the possible biosecurity risks are not limited to attempts to deliberately acquire disease samples.
- b) the potential for mishandling disease samples is low.
- c) it is possible to use the virus as a weapon of terror without extensive technical expertise.
- d) response teams are properly trained to pay close attention to both biosafety and biosecurity practices.

**4. According to Chapter 5, biosecurity measures that are implemented during a disease outbreak need to**

- a) take into account the existing international guidelines, that provide advice to response teams on managing biosecurity risks during an outbreak situation.
- b) address only the most critical vulnerabilities identified by international aid workers.
- c) be adaptable to local cultural sensitivities.
- d) be similar to traditional security measures with proven effectiveness.

**5. Which of the following statements about a collaborative outbreak response is true, according to Chapter 5?**

- a) Apart from the World Health Organization, no other international instrument/body has been involved in the efforts to foster capacity for disease response.
- b) Fostering biosecurity awareness and professional competency among practitioners and within local communities can enhance its effectiveness.
- c) Overstating the threat of bioterrorism in times of a disease outbreak plays a positive role and helps to make the public vigilant and more engaged with the response efforts.
- d) There is a limited role for local biosafety associations and other non-governmental organisations to play as part of the response.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 5, which one of the following could be considered the biggest biosecurity challenge during a major natural disease outbreak emergency:

- A. The big number of people with access to samples and other biological material;
- B. The lack of a vetting scheme for the recruitment of personnel;
- C. The risk of public unrest and potential damage to facilities and equipment used for care provision;
- D. The lack of awareness of biosecurity among health and community workers;
- E. The potential lack of appropriate laboratory equipment for storing and handling samples and other biological material;
- F. The risk of samples being stolen by accident, even if they may not be the prime goal of the criminals;
- G. The risk of a sick patient escaping a designated area under quarantine;
- H. The lack of awareness among the local population of the disease epidemic and appropriate treatment requirements.



## Second Application Exercise

### Instructions

- **Chapter 5 gives an overview of the potential biosecurity risks during a public health emergency and suggestions of possible biosecurity measures that could be taken to prevent them.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been deployed in the midst of a public health emergency taking place in a densely populated secluded rural area with limited healthcare infrastructure. The disease is not easily transmissible from person to person, but the death rate is high. As the epidemic has already spread across borders affecting several countries, there is a high risk of further spread to other regions and continents. Your team has been tasked with the development of a biosecurity action plan in the country that has been the worst affected by the epidemic so far. You have to propose at least **three** biosecurity measures suitable for the local conditions, and be able to explain to local healthcare practitioners and community workers why the measures are required, and why it is important that they follow them strictly.

### **Guiding Tips:**

- What are the potential biosecurity risks and how could a biosecurity action plan help prevent them?
- What practical approaches could be used, given the circumstances, to ensure that the public health emergency is not exploited for malicious purposes?
- What strategies would you use to explain to the people involved in care provision that biosecurity is important?
- How would you address concerns that biosecurity is not as important as saving lives and therefore does not deserve attention?
- How would you ensure that the measures you propose do not divert attention from the goal of containing the epidemic?

## **Chapter 6: The Biological and Toxin Weapons Convention and the Role of Scientists**

### **Key Learning Objectives**

- i. Understand the relevance of the Biological and Toxin Weapons Convention to life science practice;
- ii. Develop an appreciation of the strengths and limitations of the Convention;
- iii. Understand that scientists can contribute to strengthening the Convention.

### **Individual/Team Readiness Assurance Test**

#### **Instructions**

- **Based on the information provided in Chapter 6, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

#### **1. The 1925 Geneva Protocol**

- a) bans the use of chemical and biological weapons in warfare.
- b) is a non-binding agreement.
- c) is binding only on those states that have ratified it.
- d) outlaws the possession of biological weapons.

#### **2. Which of the following factors did NOT play a role in the negotiation of the 1975 Biological and Toxin Weapons Convention (BTWC)?**

- a) The use of Agent Orange by the US troops during the war in Vietnam.
- b) The fact that few states were believed to possess biological weapons at the time.
- c) Concerns over the safety of biological weapons stockpiles.
- d) The failure to agree on international arms control measures on nuclear weapons.

### **3. The Biological and Toxin Weapons Convention**

- a) makes provisions for verification of compliance.
- b) prohibits any work with certain pathogens, that can be used for the development of biological weapons.
- c) was modelled on another multilateral treaty, that was negotiated a few years earlier.
- d) allows States Parties to preserve any biological weapons, that were developed prior to joining the Convention, as long as they can be stored safely.

### **4. Which of the following statements about Confidence Building Measures (CBMs) is FALSE?**

- a) The number of states that participate in the annual exchange of CBMs is small.
- b) The CBMs provide only information about activities related to the development of biological weapons.
- c) All high-containment facilities, located within a State Party to the Convention, need to be listed in the CBMs.
- d) States Parties are required to provide information about vaccine production facilities.

### **5. Which statement BEST characterises the state of the Convention on the eve of its Eight Review Conference, to be held in 2016?**

- a) The Convention is irrelevant, given the rapid advancement of biotechnology.
- b) Although the Convention has been fully implemented, it is too weak to ensure that the life sciences are not used for hostile purposes.
- c) The Convention has universal membership.
- d) Its implementation has been enhanced by the collaborative efforts of States Parties and civil society.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 6, which one of the following is the main challenge facing the Biological and Toxin Weapons Convention in the 21<sup>st</sup> century?

- A. The emergence of new threats (e.g. bioterrorism) has rendered the Convention inadequate as a means of promoting international security;
- B. The need to ensure that the rapid advancement of biotechnology is not used for the development of biological weapons in the future;
- C. The fact that only a limited number of States Parties submit Confidence Building Measures reports on an annual basis;
- D. The fact that there are still countries which have not ratified the Convention;
- E. The destruction of all remaining stockpiles of biological weapons developed during the Cold War;
- F. The lack of a verification mechanism, which makes it impossible for states to ensure compliance with the provisions of the Convention;
- G. The need to renew the process of developing a legally-binding Protocol;
- H. The need to merge the Biological and Toxin Weapons Convention and the Chemical Weapons Convention, as initially envisaged in the late 1960s.

## **Second Application Exercise**

### **Instructions**

- **Chapter 6 offers an overview of the evolution of the Biological and Toxin Weapons Convention, its strengths and weaknesses.**
- **Read the scenario below, complete the task after it and report to the class.**

Your team has been tasked with reviewing the text of the Biological and Toxin Weapons Convention, in order to make it more effective. Based on the original text of the Convention and the information provided in Chapter 6, develop an outline of the key elements of a Convention which, in an ideal world, would be an adequate and efficient mechanism for addressing the problem of biological weapons.

### **Guiding Tips:**

- What changes do you think are required to tackle the existing deficiencies of the Convention?
- How could those changes be implemented (e.g. who would be the main stakeholders in the process of the implementation of the Convention, and what would their roles be)?
- Are there elements in the Convention that should not be changed under any circumstances?
- What additional mechanisms might be put in place to facilitate and ensure the implementation of the Convention internationally?

## Chapter 7: The Web of Prevention

### Key Learning Objectives

- i. Understand how the concept of the ‘web of prevention’ relates to life science practice;
- ii. Develop an appreciation of the key elements of the web;
- iii. Understand the need for a web of prevention approach for addressing biological security threats.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information on the Web of Prevention provided in Chapter 7, fill in Table 1 below. Arrange the different policies, initiatives, and regulations in the category that defines them best. Some items may fall in more than one category. In such cases, list them under all relevant categories.
- Total number of points: 20 (each correct answer is worth 0.8 points).

WEB OF PREVENTION					
International Prohibitions	Handling, Storage, and Export Controls	Laboratory Biosafety	Disease Detection and Prevention	Response	Preparedness

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**List of Items:**

1. Cartagena Protocol on Biosafety (Convention of Biological Diversity)
2. World Health Organization Strategic Framework for Action 2012-2016 Laboratory Biorisk Management
3. 1925 Geneva Protocol
4. Food and Agriculture Organization Emergency Prevention System
5. Green Customs Initiative
6. European Union CBRN Centres of Excellence
7. Biological and Toxin Weapons Convention
8. OIE Biological Threat Reduction Strategy
9. Global Health Security Agenda
10. United Nations Secretary General’s Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons
11. Food and Agriculture Organization Biosecurity Toolkit
12. United Nations Security Council Resolution 1540
13. International Health Regulations
14. Global Partnership against the Spread of Weapons and Materials of Mass Destruction
15. European Centre for Standardisation Workshop Agreement “Laboratory Biorisk Management”
16. Global Health Security Initiative
17. Australia Group

## First Application Exercise

### Instructions

- **Chapter 7 provides an overview of the concept of the ‘web of prevention’ and its different elements.**
- **You need to read the passage below and list all sets of rules, regulations, policies and guidelines, both national and international, which you consider applicable to the research presented in the scenario.**
- **You need to provide a rationale for your choice.**
- **You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.**

Your research team is submitting a funding proposal for a joint project with a life science group based overseas. The country where your prospective collaborators are based is not a State Party to the Biological and Toxin Weapons Convention, or to the Cartagena Protocol to the Convention on Biological Diversity. Your country is a member of the Australia Group. The project entails experiments with highly pathogenic agents that can only be conducted under strict conditions of biocontainment. To keep the project costs down, you intend to exchange samples via mail and keep in touch via online conference platforms and emails. The research is part of a global framework for combating infectious diseases and your goal will be to disseminate the research results as broadly as possible.

1. ....
2. ....
3. ....



## Second Application Exercise

### Instructions

- **Based on the information provided in Chapter 7, develop a web of prevention which includes the key relevant policies, rules, regulations, and guidelines applicable to your country.**
- **Present your findings to the class.**

### **Guiding Tips:**

- Of which international and regional agreements and treaties is your country a member, and how are they implemented nationally?
- Which aspects of life science research are regulated in your country?
- What guidelines and policies are in place in your country?
- Is your country a member of any international/regional framework initiative listed in Chapter 7?

## Chapter 8: Dual Use and Responsible Conduct of Science

### Key Learning Objectives

- i. Understand the concept of ‘dual use’, as it applies in the context of the progress of the life sciences;
- ii. Understand the need for a dialogue between the scientific community and the security community;
- iii. Develop an appreciation of the ways in which scientists can contribute to the debate on dual use and biological security;
- iv. Develop an appreciation of the need for broadening the concept of responsible science to include dual-use and biosecurity aspects.

### Individual and Team Readiness Assurance Test (iRAT/tRAT)

#### Instructions

- **Based on the information provided in Chapter 8, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

#### **1. Which statement about the meaning of “dual use” is TRUE, according to Chapter 8?**

- a) Traditionally “dual use” refers to the risk of hostile misuse of novel scientific advances.
- b) It has not changed in the aftermath of 9/11 and the anthrax letter attacks.
- c) According to the Fink Committee report, “dual use” is a non-normative, value-free term.
- d) It originally encompassed technology that has both civilian and military use.

#### **2. According to the Fink Committee report,**

- a) existing domestic and international guidelines for the conduct of basic research were not sufficient to ensure physical safety and prevent exposure to pathogens.
- b) no national or international authority existed for assessing the risks associated with the potential for misuse of proposed research.
- c) additional regulations constitute the most effective way to address the dual-use dilemma.

- d) self-governance by the life science community could not help tackle the dual-use dilemma.

**3. Which of the following statements is FALSE, according to Chapter 8?**

- a) Several professional and learned societies have developed codes of ethics/conduct to prevent the hostile misuse of life science knowledge and materials.
- b) The Fink Committee report defined seven categories of experiments of concern, that required additional review before being conducted.
- c) Besides the USA and the UK, no other country has explicitly expressed support for codes of conduct.
- d) Measures for engaging life scientists with biosecurity and dual-use issues have been discussed within the framework of the Biological and Toxin Weapons Convention (BTWC).

**4. The Lemon-Relman Committee report**

- a) argued that all life science research should be analysed with regard to dual-use potential.
- b) recommended the establishment of the National Science Advisory Board for Biosecurity (NSABB) in the USA.
- c) is the only authoritative report to link neuroscience research with potential military applications.
- d) focused on identifying experiments of concern in microbiology and virology.

**5. Which statement BEST summarises the main challenge to fostering dialogue between the life science and security community?**

- a) The security community tends to rely upon fictional scenarios about bioterrorism attacks, and thus exaggerates the potential risks.
- b) It is not clear how tacit knowledge impacts on life science research and the potential for misuse.
- c) The security community has shown little interest in engaging with the life science community.
- d) The life science community has not been sufficiently exposed to issues of dual use and biosecurity as part of their education.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 8, which option best explains the low engagement among life scientists with issues of biosecurity and dual use over the past ten years, despite the publication of high-level reviews such as those produced by the US National Academy of Sciences and the UK Royal Society?

A. Life scientists have never been involved in discussions on the broader social, ethical and security implications of their work.

B. There is no need for scientists to be involved in biosecurity discussions: scientists should do science; decisions regarding life science oversight should be made by governments.

C. Biosecurity is not about the life sciences; it is about hypothetical nightmare-style scenarios, which misrepresent science and seek to create panic among the public.

D. The majority of the life science community is well aware of biosecurity, but does not share the concerns of the security community.

E. Most discussions on biosecurity are dominated by the security community, and deliberately exclude life scientists.

F. It is very difficult for life scientists to get involved in biosecurity, as there are virtually no formal mechanisms that could facilitate their engagement with security concerns.

G. Life scientists are rarely exposed to issues of biosecurity during their formal education.

H. Biosecurity is of no relevance to the majority of life scientists, as it only relates to a limited number of experiments with highly dangerous pathogens.

## Second Application Exercise

### Instructions

- **Chapter 8 describes the problem of the low engagement among life scientists with biosecurity. The chapter also highlights the need for improving the dialogue between the life science community and the security community.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been nominated to serve as a biosecurity working group at your institution. As part of your duties, you have been tasked with the development and implementation of a code of conduct for biosecurity. You have to prepare **both** the code **and** an action plan on how it would be promulgated within your institution.

### **Guiding Tips:**

- What are the purpose, scope, key messages, and aims of the Code?
- Who is the target audience?
- What key responsibilities of life scientists with regard to biosecurity should be listed, and how do those relate to research practice?
- What actions should be taken to fulfil those responsibilities? What processes should be in place to ensure that any biosecurity risks are properly managed?

### **Also acknowledge:**

- How would the Code be promulgated?
- How would you ensure compliance with the Code?
- How would you persuade your colleagues that such a Code would serve their interests, and not be another bureaucratic burden?

## Chapter 9: Convergence of Chemistry and Biology, Security Risks, and the Role of Industry

### Key Learning Objectives

- i. Understand the security issues arising from the convergence of chemistry and biology, and how those impact on the Biological and Toxin and Chemical Weapons Conventions;
- ii. Develop an appreciation of the strengths and weaknesses of the Conventions in the context of the progress of the chemical and biological sciences;
- iii. Understand how industry can contribute to strengthening the Biological and Toxin and Chemical Weapons Conventions;

### Individual and Team Readiness Assurance Test (iRAT/tRAT)

#### Instructions

- Based on the information provided in Chapter 9, fill in the table below, listing the characteristics of the Biological and Toxin Weapons Convention and the Chemical Weapons Convention, as specified for each category.
- Total number of points: 20 (each correct answer is worth 1.4 points).

Category	Biological and Toxin Weapons Convention	Chemical Weapons Convention
Scope (e.g. what is prohibited)		
Implementing Institution		
Verification		
Proceedings		
Review of Science and		

<b>Technology</b>		
<b>Review of Progress of Work</b>		
<b>Industry Involvement</b>		

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 9, which one of the following aspects of the convergence of biology and chemistry poses the single most fundamental challenge to the existing international biological and chemical disarmament regime:

- A. Convergence gives rise to new areas of research that are not covered by either the Biological and Toxin Weapons Convention or the Chemical Weapons Convention.
- B. Biology is gradually evolving from a descriptive to a predictive discipline, offering a range of tools that can be used to design organisms with desired properties.
- C. More and more companies around the world are applying chemical and biological processes in industrial production.
- D. The increasing diffusion of expertise and de-skilling has enabled a large number of scientists globally to conduct cutting-edge research, leading to more intense cross-border collaboration.
- E. It is difficult to evaluate at political level what the real impact of convergence for chemical and biological disarmament is, and how it should be best addressed to ensure compliance with the international prohibitions.
- F. Top-down regulation in the area of convergence is not sufficient to prevent the hostile misuse of relevant knowledge and materials.
- G. There is a lack of close ties between the pharmaceutical industry and the Biological and Toxin Weapons Convention.
- H. The governance of the convergence of biology and chemistry can not be effective, as long as the international prohibition of chemical weapons is kept separate from the prohibition of biological weapons.



## Second Application Exercise

### Instructions

- **Chapter 9 gives an overview of the risk and benefits, that have arisen from the convergence of chemistry and biology.**
- **It also highlights the role that the chemical industry has played in the development and maintenance of the Chemical Weapons Convention.**
- **Read the scenario below, complete the task and report to the class.**

You and your fellow team members are all CEOs of different biotechnology and pharmaceutical companies. You are fascinated by the rapid progress of science and technology, and are convinced that the convergence of chemistry and biology holds a significant potential for innovation and profit. At the same time, you are conscious of the reports and literature on the potential risks of new S&T advances, and are well aware of the devastating effects that a biological incident, whether caused by accident or deliberately, could have on your company. For this reason, you want to make sure that you have certain measures in place, in order to mitigate biological security risks. You have consulted colleagues in the field, and together you have decided to convene a meeting to discuss how best to approach the issue. The purpose of the meeting is to develop a strategy with a set of recommended actions that your respective companies can take, in order to promote biological security. What would the key elements of that strategy be? What actions would you recommend should be taken?

### **Guiding Tips:**

- What is the scope of the problem you are trying to address?
- Which international and national regulations would be relevant?
- Would you consult other stakeholders and, if yes, who would they be?
- Are there lessons you could take from the involvement of the chemical industry in the negotiations of the Chemical Weapons Convention and, if yes, what are they?
- How would be the new strategy implemented? What institutional measures would there be to ensure that new practices are adopted?
- How would you ensure that your staff are properly informed of the new measures, and that they have the appropriate training to implement them?
- How would you raise awareness of your strategy among other companies?

# Chapter 10: International and National Scientific Organisations, and Biological Security

## Key Learning Objectives

- i. Understand that scientific organisations can contribute to promoting and strengthening biological security;
- ii. Develop an appreciation of the ways in which scientists, through their respective national and international organisations, can participate in the Biological and Toxin Weapons Convention.

## Individual/Team Readiness Assurance Test

### Instructions

- Based on the information provided in Chapter 10, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

### 1. Which statement about codes of conduct is FALSE, according to Chapter 10?

- a) They have been discussed within the framework of the Biological and Toxin Weapons Convention on several occasions.
- b) Several national academies of sciences and professional societies have developed codes of conduct, relevant to biosecurity.
- c) The first universal code of conduct on biosecurity for life scientists was issued in 2005.
- d) Scientists have been actively involved in the development of codes of conduct.

### 2. The Global Network of Science Academies (IAP)'s statement on biosecurity

- a) does not specifically refer to the Biological and Toxin Weapons Convention.
- b) asserts that life scientists should not be held responsible if their work is misused.
- c) gives an example of how a code of conduct should be structured.
- d) highlights that all life scientists have an ethical duty with regard to biosecurity.

### **3. According to Chapter 10, there is little evidence that**

- a) scientific organisations have made a significant effort to develop strategies for promoting biosecurity.
- b) junior scientists can get involved in the work of scientific organisations and professional bodies, and thus contribute to policy formation.
- c) codes of conduct can be an important tool for engaging life scientists with biosecurity.
- d) the number of faculty and instructors sufficiently knowledgeable to teach about biosecurity and dual-use issues is low.

### **4. Educational / Advisory codes**

- a) set out ideals that practitioners should uphold.
- b) are typically embedded within wider systems of legal regulation.
- c) are compulsory mechanisms which exist in all laboratories around the world.
- d) are often designated as ‘codes of conduct’.

### **5. The IAP Biosecurity Working Group**

- a) convened its first international workshop on developments in science relevant to the Biological and Toxin Weapons Convention in 2011.
- b) drew inspiration from the work of the International Union of Pure and Applied Chemistry (IUPAC).
- c) has failed to produce an authoritative assessment of the implications of science and technology for biological security and disarmament.
- d) has faced considerable challenges in bringing together life scientists, due to the diversity and fragmentation of the field.

## First Application Exercise

### Instructions

This exercise involves the choice of two options from a list.

- You need to agree, write down and submit your best answers for the task AND your rationale for each answer e.g. why you have chosen an option, the criteria for your choices or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information on the role of scientific organisations in promoting biosecurity presented in Chapter 10, which of the following are the **two** most important functions of national and international scientific organisations with regard to biosecurity?

- A. To provide a link and channels of communication between science and the government/governments
- B. To provide a link and channels of communication between science and the public
- C. To provide expert advice on relevant issues
- D. To promote development of the norm against misuse of biology
- E. To serve as arbiters of biosecurity debates within the scientific community and provide conclusive answers
- F. To offer policy recommendations on relevant biosecurity issues
- G. To provide a broad platform for discussion of biosecurity issues, by bringing together experts from various disciplines
- H. To foster discussion on various biosecurity issues among scientists and other relevant stakeholders

## Second Application Exercise

### Instructions

- **Chapter 10 gives several examples of the activities of scientific organisations aimed at engaging life scientists with biosecurity.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been chosen to serve as an organising committee of an international meeting that seeks to (1) identify developments in science and technology relevant to the Biological and Toxin Weapons Convention; (2) assess their impact on the Convention; and (3) offer recommendations to the States Parties of the Convention on any actions that need to be taken. Prepare a plan taking into account the following points:

1. Size of the meeting: number of participants, duration, venue.
2. Scope of participation: criteria for selection of participants (e.g. age, field of specialisation, background, experience with biosecurity etc.). What steps would you take to ensure adequate representation in terms of geography/expertise/opinions?
3. Agenda: how would you ensure that the agenda of the meeting fulfils the objectives of the meeting set above? What topics would be addressed? What sort of representatives would you invite as speakers?
4. Outcomes: how would the results of the meeting be summarised? Who would be responsible for drafting the report? How would you ensure that the report adequately represents the outcomes of the meeting?
5. Presentation: how would the findings be presented and by whom? How would you ensure that the findings are broadly disseminated (e.g. to whom would they be of interest, and how would you reach out to any interested parties?)

# Chapter 11: Review of Scientific and Technological Developments, and the Biological and Toxin Weapons Convention

## Key Learning Objectives

- i. Understand the strengths and weaknesses of the existing mechanisms for reviewing scientific and technological developments under the Biological and Toxin Weapons Convention;
- ii. Develop an appreciation of how scientists can contribute to improving the review of scientific and technological developments, relevant to the Biological and Toxin Weapons Convention;

## Individual/Team Readiness Assurance Test

### Instructions

- Based on the information provided in Chapter 11, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

### 1. The primary role of the BTWC Implementation Support Unit (ISU) is to

- a) serve as the Convention's implementing agency.
- b) oversee compliance with the BTWC
- c) coordinate the activities of civil society in support of the BTWC.
- d) provide administrative assistance and facilitate communication among stakeholders.

### 2. Which statement about the review of science and technology, as part of the work of the BTWC, is FALSE?

- a) During Review Conferences, relevant S&T developments are usually considered as part of the review of Article 1 of the Convention.
- b) Review reports, that were prepared by the civil society were circulated among States Parties at the Sixth and Seventh Review Conferences.
- c) A significant number of States Parties submit information on reviews of science and technology.
- d) Before the Seventh Review Conference of the BTWC, reviews were conducted once every five years.

**3. Which of the following characteristics does NOT apply to the review process, that was agreed by States Parties in 2011:**

- a) S&T developments are discussed under a Standing Agenda Item each year.
- b) The ISU was formally tasked with the preparation of relevant background.
- c) The review is structured thematically.
- d) The technical review is carried out at the BTWC Meetings of Experts.

**4. Since 2008, BTWC Meetings of Experts have included**

- a) a poster session.
- b) an essay competition.
- c) a key note opening address by a prominent scientist.
- d) a whole day workshop on S&T.

**5. When attending a BTWC meeting as representatives of non-governmental organisations, scientists cannot**

- a) observe public parts of the meetings.
- b) make a statement during an informal session.
- c) speak as Guests of the Meeting without a prior invitation.
- d) organise a side event.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 11, which of the following is the main weakness of the existing mechanisms under the Biological and Toxin Weapons Convention for review of developments in science and technology:

A. Scientists cannot contribute directly to the Meetings of the Convention held as part of the Intersessional Programme;

B. The Implementation Support Unit has played only a marginal role in engaging life scientists with the Convention;

C. The structure of the Intersessional Programme does not allow for science and technology review to take place;

D. The review is being conducted only once every five years during the Review Conference;

E. The review of science and technology is not formally discussed at the Meetings of the Convention;

F. Even though States Parties submit an extensive amount of information on the review of science and technology, the Implementation Support Unit does not have the capacity to analyse it;

G. There is low interest within the life science community in participating and contributing to the work of the Biological and Toxin Weapons Convention;

H. There are no formal structures within the Convention through which life scientists could contribute to the process of science and technology review.



## Second Application Exercise

### Instructions

- **Chapter 11 gives an overview of the activity of the Implementation Support Unit and its role in the review of science and technology.**
- **It also provides information on the way in which life scientists can contribute to the process.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been selected to serve as an expert-level working group tasked with the assessment of developments in science and technology relevant to the Biological and Toxin Weapons Convention. You have to choose **one** area/development/technique and identify its potential benefits and risks for the Convention. Prepare at least **two** recommendations to States Parties regarding any action needed for addressing this development, to ensure that it is utilised only for peaceful, prophylactic and protective purposes.

### **Guiding Tips:**

- Your role is to represent the scientific community in policy-making. You are expected to help government officials and diplomats develop an appreciation of the possible risks and benefits of novel biotechnology, and suggest ways of dealing with them effectively.
- Think about your target audience and their potential knowledge of science. How would you structure your assessment report to ensure that your audience fully understands the message you are trying to convey?
- How would you ensure that your assessment is balanced?
- Once you have completed the assessment, think about what needs to be done to balance and secure the potential benefits of the given development against the possible risks.
- When devising your suggested solutions, think about whether there is a measure that could be particularly detrimental to science, and that you would like to avoid at any cost. At the same time, think about what measures would allow you to ensure that the public does not lose its trust in the scientific community.

## **Chapter 12: Building Sustainable Partnerships between the Scientific and Law Enforcement Communities**

### **Key Learning Objectives**

- i. Develop an appreciation of the need for fostering partnerships between the law enforcement community and the scientific community;
- ii. Understand how law enforcement agencies and scientists can collaborate on minimising the potential security risks, arising from the advancement of science and technology;
- iii. Develop an appreciation of the ways in which law enforcement agencies seek to outreach to the scientific community.

### **Individual/Team Readiness Assurance Test**

#### **Instructions**

- **Based on the information provided in Chapter 12, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

#### **1. Which of the following is NOT among the core tenets of the FBI Biosecurity engagement effort?**

- a) As far as national security is concerned, the mission of the law enforcement community is primary, and that of the scientific community - secondary.
- b) It is important to foster partnerships through mutual understanding and trust.
- c) The biosecurity measures implemented need to be practical and commensurate to the potential threat, without unnecessary stifling innovation.
- d) A combination of different experiences and expertise allows the development of preventive measures that evolve with the threat spectrum.

#### **2. When first introduced in 1997, the US Federal Select Agents Regulations (SAR)**

- a) applied only to a limited number of bacteria and viruses.
- b) required any facilities working with such agents to be registered with the Federal Select Agent Program.
- c) were administered by the FBI.

- d) established an oversight mechanism for agents likely to have severe impact, if released accidentally or deliberately.

**3. Based on the FBI experience, which of the following lessons learned is TRUE?**

- a) The life science community needs to be involved in the development of biosecurity policies and regulations.
- b) It is not essential for the life science community to be involved in the development of biosecurity policies and regulations, as long as information about the outcome documents is shared immediately.
- c) It is sufficient that the life science community is consulted, once the biosecurity policies and regulations are drafted.
- d) It should be left up to the life science community to develop biosecurity policies and measures, and the law enforcement community should be consulted only if necessary.

**4. Personnel reliability programmes (PRP) related to the SAR**

- a) apply to anyone with access to select agents.
- b) involve the collection of information that extends beyond professional and technical competency.
- c) have been widely favoured by the scientific community as a necessary measure to enhance security.
- d) Should cover only pre-employment suitability.

**5. Which statement is FALSE, according to Chapter 12?**

- a) Some of the FBI members of staff working on biosecurity are trained as scientists.
- b) The screening of orders of synthetic DNA is governed through a voluntary protocol.
- c) Institutional Biosafety Committees were first established in response to the H5N1 controversy.
- d) Through their engagement with iGEM, the FBI has managed to reach out to amateur biologists.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen a particular option.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information in Chapter 12, which one of the following statements best describes the relationship between the life science community and national law enforcement agencies, given the security risks arising from biotechnology:

A. There is no need for a new relationship; research is the domain of the life science community; law enforcement agencies should be focused on crime investigation;

B. The development of life science regulations is the domain of the state, and the life science community need not be included in the process; law enforcement agencies should only intervene if there is a suspicion that the rules are not properly observed;

C. Law enforcement agencies should take any measures necessary to ensure national security, including full background checks, psychological testing, and if necessary censorship; life scientists should comply with those requirements;

D. The life science community should rely upon self-regulation and alone decide what measures need to be taken to prevent bioterrorism, in order to prevent unnecessary infringement of academic freedom;

E. Close collaboration between the life science community and law enforcement agencies is essential only in time of an emergency;

F. Law enforcement agencies should conduct regular inspections to ensure that the biosecurity rules and procedures are strictly followed and properly implemented; during such inspections, the life science community should offer full cooperation;

G. The life science community needs to be actively involved in the development and implementation of biosecurity rules; law enforcement agencies should facilitate this process, through outreach about the possible risks and the need for taking countermeasures;

H. There is a need for close collaboration: a law enforcement representative should be deployed at every life science research facility, and serve as a designated person for the implementation of a biosecurity programme, and for monitoring compliance with the rules in place.

## Second Application Exercise

### Instructions

- **Chapter 12 offers an overview of a range of activities designed to enhance the cooperation between the life science community and law enforcement agencies and promote biosecurity through mutual understanding.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been recruited by a local law enforcement agency to provide expert advice on the development of an outreach programme, designed to promote engagement with the life science community. Your task is to develop an outreach strategy aimed at raising awareness among life scientists of the possible security risks of interest to law enforcement, and explaining the need for implementing adequate countermeasures.

### **Guiding Tips:**

- What measures would be necessary (e.g. background checks, medical examination, facility/individual licensing, registration)?
- Who would be your target audience (e.g. science students, practising researchers)?
- How would you approach relevant facilities/individuals? What kind of outreach activities do you envision?
- What tools and approaches would you use to raise awareness of the risks?
- What measures would be put in place to ensure that the relationship you aim to build is sustainable?

## Chapter 13: Multisectoral Coordination and Biological Security

### Key Learning Objectives

- i. Understand the need for inter-agency collaboration and dialogue on strengthening biological security and enhancing preparedness;
- ii. Develop an appreciation of the multifaceted activities that law enforcement agencies can perform, in order to engage stakeholders in biological security;
- iii. Understand the role that scientists can play in enhancing multisectoral coordination for biological preparedness.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information provided in Chapter 13, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

**1. Which of the following statements about biosecurity in a changing world is FALSE, based on the information provided in Chapter 13?**

- a) There is a growing concern among law enforcement, governments, and public health officials around the world that biological materials may be used for unlawful acts.
- b) There is no objective information that suggests that terrorist groups may be interested in using biological materials.
- c) Access to knowledge and biological materials for nefarious purposes has become much easier through the 'Darknet'.
- d) Striking a balance between academic freedom in the form of publication and security is a persistent challenge that could possibly increase the risk of misuse of biological materials.

**2. Among the key findings of the first meeting convened by INTERPOL to discuss bioterrorism prevention was that**

- a) law enforcement agencies and public health had to collaborate on enhancing preparedness.

- b) law enforcement agencies had to develop in-house capacity, in order to deal with bioterrorism incidents on their own.
- c) defence scientists working with the military had to take the lead in any investigation, where there is a suspected use of biological materials.
- d) any suspected case of bioterrorism had to be investigated by INTERPOL.

**3. The use of table top exercises during Operation S<sup>3</sup>oMMET has aimed to:**

- a) enhance participants' understanding of how to draft effective bioterrorism legislation.
- b) promote the development and use of cost-effective biosecurity measures.
- c) highlight the role of communication among stakeholders.
- d) strengthen capacities for surveillance.

**4. Physical security measures include**

- a) proper labelling when sending pathogens abroad.
- b) restricting access to certain web pages on computers, that are found within a laboratory.
- c) monitoring staff performance.
- d) keeping records of all specimen and cultures, that have been shipped to the laboratory over the past several years.

**5. When developing personnel reliability programmes, attention should be given to:**

- a) obtaining credit information and medical records from employees on a regular basis.
- b) monitoring only individuals who exhibit deviant behaviour.
- c) screening measures that allow for early identification of issues related to stress factors and personal, financial, or health problems.
- d) ensuring that long-established employees are subject to the same level of scrutiny and checks as new comers and prospective recruits.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 13, which one of the following options best describes the most important element of an effective biosecurity law enforcement system?

- A. Training law enforcement personnel in best practice for bioterrorism investigation.
- B. Ensuring appropriate physical security measures at high-containment laboratories and other relevant research facilities.
- C. Introducing adequate measures for scientific data protection and information security at designated facilities.
- D. Educating the public about bioterrorism prevention.
- E. Close collaboration among national law enforcement agencies to prevent biosecurity risks globally.
- F. Developing a robust legal framework.
- G. Building close partnerships among national law enforcement agencies, the public health service and academia.
- H. Focusing on disease surveillance for bioterrorism prevention.



## Second Application Exercise

### Instructions

- **Chapter 13 gives a detailed overview of INTERPOL's activities aimed at strengthening biosecurity and fostering sustainable capacity for the prevention of biological threats.**
- **It also outlines a set of core principles for the prevention and mitigation of future biosecurity threats.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been nominated to serve as a Government Advisory Committee on Bioemergency Prevention, Planning and Response. You have been tasked to prepare a national biosecurity action plan that aims to improve coordination among the various stakeholders involved, and to ensure effective prevention against biological threats, especially deliberate misuse of life science knowledge and materials for malevolent purposes. Present your action plan in the form of a diagram, table or a map to indicate possible areas of collaboration among the relevant stakeholders.

### **Guiding Tips:**

- List all stakeholders you consider relevant to the prevention of biosecurity threats.
- Identify relevant measures that need to be taken at each stage, i.e. prevention, control, planning, detection, response etc.
- Identify the responsibilities of each relevant stakeholder with regard to the suggested measures.
- How would coordination among the different activities be achieved?
- How would you ensure that the proposed system is sustainable?

# Chapter 14: National Implementation of Biosecurity: A Case Study of Denmark

## Key Learning Objectives

- i. Understand the measures, that have been introduced in Denmark for strengthening biosecurity;
- ii. Develop an appreciation of the ways in which governments can outreach to, and engage, industry in biosecurity;
- iii. Understand the range of measures that laboratories and research facilities can implement to enhance biosecurity, and thus minimise the risk of hostile misuse of life science knowledge and materials.

## Individual/Team Readiness Assurance Test

### Instructions

- Based on the information provided in Chapter 14, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

### 1. The Abrin case described in Chapter 14 highlights

- a) how difficult it is to obtain biological material illicitly.
- b) that it is impossible to detect illicit trade in potentially dangerous biological agents.
- c) the need for a coordinated governmental response in preventing, detecting, and responding to the potential misuse of biological agents.
- d) the challenges of shipping biological agents when the customer is located overseas.

### 2. The provisions of the Biosecurity Act and Executive Order No.981 require \_\_\_\_\_ wishing to work with biological dual-use components to apply for and acquire a licence.

- a) scientists
- b) companies
- c) universities
- d) laboratories

**3. Each entity with a CBB licence must have a biosecurity officer. The biosecurity officer**

- a) has to be trained by the CBB.
- b) is appointed by the CBB.
- c) does not require any specific qualifications.
- d) is in charge of conducting regular in-house inspections.

**4. Security installations, stock management, transportation security, and \_\_\_\_\_ are physical elements in the Danish biosecurity model?**

- a) security culture
- b) information security
- c) access control
- d) an ethical code

**5. Which of the following is NOT within the scope of responsibilities of the CBB?**

- a) Undertaking inspections of certified facilities.
- b) Raising awareness of biosecurity within Danish universities.
- c) Monitoring new developments in science and technology that could have an impact on biosecurity.
- d) Managing all certified facilities to ensure compliance.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 14, which one of the following is the most important feature of the Danish system for biosecurity that ensures its effectiveness?

- A. It is enforceable by national law.
- B. There is a single implementing agency – the Centre for Biosecurity and Biopreparedness – that coordinates all activities related to biosecurity nationally.
- C. Companies conducting activities with biological dual-use material are required to apply for a licence.
- D. Companies holding a licence are responsible for ensuring biosecurity at their own premises; the Centre for Biosecurity and Biopreparedness does not micromanage every single company with a licence.
- E. It relies on binding and non-binding measures that address both the physical and non-physical aspects of biosecurity: e.g. licensing, inspections, outreach efforts, dialogue between government officials and company representatives.
- F. The regulations recognise three types of controlled technology; appropriate measures, ranging from licensing to awareness-raising, are applicable accordingly.
- G. The Centre for Biosecurity and Biopreparedness conducts research in order to better understand what kind of new threats could emerge in future.
- H. The Centre for Biosecurity and Biopreparedness is actively involved in international cooperation on sharing experience and lessons learned.

## Second Application Exercise

### Instructions

- Chapter 14 gives a detailed overview of the elements and functioning of the Danish system for biosecurity.
- Companies working with biological dual-use materials are required to have a licence and maintain appropriate biosecurity arrangements on their premises.
- Read the scenario below, complete the task and report to the class.

Your team is serving as the senior management of a vaccine company based in Denmark. Research and development work is carried out in BSL-2 and BSL-3 facilities, where potentially dangerous pathogens are handled and stored. Your application for a licence has been successful, and you are allowed to start operating in the country. However, you are conscious that you will be inspected at some point to demonstrate that the biosecurity arrangements put in place are in accordance with the law. To this end, you have decided to develop a detailed biosecurity strategy/action plan outlining the necessary measures/steps/operating procedures which would demonstrate that biosecurity is properly implemented in your company. **What would those measures/steps/operating procedures be? How are they to be implemented?**

### **Guiding Tips:**

- What institutional arrangements and designated personnel would be required?
- What physical biosecurity measures would be required for the BSL-2 and BSL-3 facilities, respectively?
- How would you explain the need for biosecurity to your staff?
- How could the Centre for Biosecurity and Biopreparedness assist you in the implementation biosecurity?
- What measures could your staff take to maintain compliance with biosecurity?

## Chapter 15: Sustainable Implementation of Biosecurity through, National, Regional, and International Partnerships: A Case Study of Jordan

### Key Learning Objectives

- i. Understand how Jordan implements biosecurity nationally;
- ii. Develop an appreciation of the challenges to the implementation of biosecurity in Jordan and the efforts made to address them;
- iii. Understand how stakeholders can collaborate on a national level, in order to raise awareness of biosecurity and promote relevant policies and measures.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information provided in Chapter 15, fill in the table below, identifying the key stakeholders in the national implementation of biosecurity in Jordan and their respective functions.
- Total number of points: 20 (each correct answer is worth 0.6 points)

Stakeholder	Government Agency / Civil Society	Key Functions/Activities
		1. 2.
		1. 2.
		1. 2.
		1.

		2.
		1. 2.
		1. 2.
		1. 2.
		1. 2.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 15, what is the most significant challenge to the implementation of biosecurity in Jordan?

- A. The continuing political instability in the region and the inflow of refugees;
- B. The emergence of new infectious diseases;
- C. The need for an assessment of the current state of biosecurity in the country;
- D. The limited awareness among life scientists of biosecurity;
- E. The need for a national biosecurity policy and regulatory framework.
- F. The need for long-term funding, particularly in the area of education and capacity building;
- G. The lack of foreign assistance;
- H. The limited engagement with the private sector.



## Second Application Exercise

### Instructions

- **Chapter 15 gives an overview on the efforts to implement biosecurity in Jordan.**
- **It also highlights the importance of a national policy framework and regulations.**
- **Read the scenario below, complete the task and report to the class.**

You and your fellow team members are part of an expert-level task force, which has been formed to assist the Jordanian Government in the development and implementation of a national biosecurity policy. Your task is to identify **three** key areas which need to be strengthened, with regard to biosecurity in Jordan. You need to (1) provide a rationale for each of the areas you have selected; (2) suggest at least **two** measures that can help resolve the issues; and (3) outline an action plan for how the measures would be implemented.

### **Guiding Tips:**

- The areas of choice could be technical, e.g. sample security; logistical, e.g. lack of awareness; or organisational, e.g. improving coordination among stakeholders. You can choose as many areas of each type as you like.
- Where appropriate, identify relevant international agreements/guidelines/documents.
- For each area, identify key stakeholders that need to be engaged/consulted, and time-frame for the implementation of the actions required.
- For each action plan, explain how sustainability would be achieved.

# Chapter 16: National Implementation of Biosecurity and the Role of Scientists (1): A Case Study of South Africa

## Key Learning Objectives

- i. Develop an appreciation of the ways in which South Africa is implementing biosecurity;
- ii. Understand the role that scientists and scientific organisations can play in strengthening biological security, taking into account individual states' circumstances;
- iii. Understand the challenges that developing countries face in implementing biosecurity.

## Individual/Team Readiness Assurance Test

### Instructions

- Based on the information provided in Chapter 16, answer the following multiple-choice questions. Only one answer can be chosen.
- Total number of points: 20.

### 1. Which statement about the offensive biological weapons programme of South Africa, Project Coast, is FALSE?

- a) There is some evidence that genetic engineering research was conducted for the purposes of developing biological agents that would selectively target certain ethnic groups.
- b) Commercial companies were used to cover up offensive activities.
- c) Special attention was given to the development of non-lethal agents for suppressing dissent.
- d) South Africa was not a State Party to the Biological and Toxin Weapons Convention when the programme began.

### 2. The findings of the Truth and Reconciliation Commission about Project Coast showed that

- a) the Project was carried out without approval by the then Government of South Africa.
- b) the Project was largely designed and executed by a single individual.
- c) most civilian scientists who took part in the Project were coerced to do so.
- d) the Project was directed exclusively against external threats.

**3. According to the 2013 survey conducted by the Academy of Science of South Africa,**

- a) there is a need for enhancing communication between life scientists and policy-makers.
- b) there is little interest among life scientists in South Africa in biosecurity and dual-use issues.
- c) the existence of extensive biosecurity legislation is a prerequisite for high level of awareness of biosecurity among life scientists.
- d) the existing arrangements for the protection of whistleblowers are sufficient and effective.

**4. Which of the following characteristics does NOT apply to the context of South Africa?**

- a) Most biosecurity training is dependent on the existence of ‘champions’.
- b) The term ‘biosecurity’ is used differently in governmental publications, which may create confusion.
- c) Most bioethics lecturers are reluctant to include biosecurity and dual-use issues in their teaching.
- d) Most activities in biosecurity education have been conducted with short-term funding.

**5. The case of South Africa shows that**

- a) it is very difficult for a country, that has been involved in the development of biological weapons, to establish a biosecurity regime.
- b) national governments have a marginal role to play in biosecurity control.
- c) being a State Party to a disarmament regime is sufficient to demonstrate compliance with the resultant international obligations.
- d) transparency and multifaceted oversight can help ensure that commitments made by the government are upheld.

## First Application Exercise

### Instructions

This exercise involves choice of one option from a list.

- You need to agree, write down and submit your best answer for the task AND your rationale for the answer e.g. why you have chosen an option, the criteria for your choice or the points you considered when reaching a decision.
- You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible. Reveal your answers as directed.

Based on the information provided in Chapter 16, which one of the following options best summarises the biggest challenge to the implementation of biosecurity in South Africa?

- A. The legacy of Project Coast and the involvement of life scientists in the development of biological weapons.
- B. The lack of a single accepted definition of biosecurity.
- C. The lack of appropriate legal arrangements that ensure the protection of whistle-blowers within the life science community.
- D. The need for an oversight system featuring adequate mechanisms for raising awareness among the life science community, and dialogue between the government, life scientists, and the public.
- E. The fact that life scientists of low- and middle-income countries are more often than not under-represented in international discussions on biorisk and biosecurity.
- F. Scarcity of funding and preference for short-term projects with very broad agendas.
- G. The perception that ‘dual use’ is a Western problem and should not be considered as such an urgent priority as the treatment of infectious diseases, including HIV/AIDS and malaria.
- H. There are no major challenges; the existence of comprehensive biosecurity education domestically is a sufficient condition for a biosecurity culture in life science practice.

## Second Application Exercise

### Instructions

- **Chapter 16 gives an overview on the efforts to engage life scientists with biosecurity in the context of low- and middle-income countries.**
- **It also highlights the potential hurdles that such efforts may encounter, and the crucial role that professional associations and epistemic communities can play to help overcome them.**
- **Read the scenario below, complete the task and report to the class.**

Your team has been nominated to serve as an advisory committee to the National Academy of Science in a low-income country. The country's government is interested in the implementation of biosecurity, and has passed several national laws relevant to the Biological and Toxin Weapons Convention and UN Security Council Resolution 1540. However, the Academy has recently conducted a comprehensive nation-wide survey, which has indicated that the level of awareness of biosecurity among life scientists is low. As a first step toward engaging researchers with biosecurity, the Academy envisages a series of awareness-raising seminars, and has asked your committee to help with the organisation of the pilot seminar. Your task is to prepare an example that illustrates the significance of biosecurity to students and practitioners in a low-income country, and shows that this is not just a 'Western' problem.

### **Guiding Tips:**

- Define your target audience: e.g. students, practising life scientists, biosafety personnel etc.
- Take into account the socio-economic circumstances of the country and the facts that healthcare and research infrastructure may be of poor quality, and that resources may be stretched to the limit in an attempt to tackle public health concerns. Against this backdrop, biosecurity may not be a top priority.
- Think of ways how to demonstrate to life scientists that their engagement with biosecurity matters both for the implementation of national laws and for fostering responsible conduct of research.

## **Chapter 17: National Implementation of Biosecurity and the Role of Scientists (2): A Case Study of Canada**

### **Key Learning Objectives**

- i. Develop an appreciation of the legal framework introduced in Canada, with regard to biosafety and biosecurity;
- ii. Understand how governmental agencies can outreach to the scientific community, in order to promote awareness of novel regulations, and thus facilitate their implementation;
- iii. Understand the ways in which scientists can collaborate with governmental agencies, in order to foster a culture of biosafety and biosecurity.

### **Individual/Team Readiness Assurance Test**

#### **Instructions**

- **Based on the information provided in Chapter 17, answer the following multiple-choice questions. Only one answer can be chosen.**
- **Total number of points: 20.**

**1. Which statement about Canada's biosafety and biosecurity oversight system is FALSE?**

- a) There are provisions for mandatory registration of all laboratories in possession of human pathogens and toxins.
- b) The Public Health Agency of Canada is the single national point for laboratories working with human and/or terrestrial animal pathogens.
- c) Relevant standards and guidelines are available in the form of mobile phone and web applications.
- d) It does not cover risks posed by synthetically produced human pathogens, gain-of-function research, or research with dual-use capabilities.

**2. Which of the following sectors is NOT involved in the whole of government approach to pathogen biosafety and biosecurity?**

- a) The Ministry of Education.
- b) The security intelligence services.
- c) The police.
- d) Food inspection authorities.

**3. In order to address the tension between the need for innovation and regulatory oversight, the Public Health Agency of Canada (PHAC):**

- a) developed an online training course focussing on the risks and benefits of research with dual-use capabilities.
- b) held a series of meetings with universities across the country, that brought together the academic community with public health, security, and intelligence partners.
- c) issued recommendations that all laboratories should adopt codes of conduct for biosecurity.
- d) made university laboratories exempt from the new regulations.

**4. A Biological Safety Officer**

- a) is designated only after the appropriate licence has been granted to the applicant institution.
- b) is required only at institutions where work with highly dangerous pathogens is carried out.
- c) functions as a key compliance and monitoring resource for the licence holder.
- d) is nominated by the Public Health Agency of Canada (PHAC).

**5. Canada's experience with the development of biosafety and biosecurity oversight highlights**

- a) the need for limiting legally-binding obligations upon research institutions and related facilities.
- b) the need for dividing the responsibilities for administration of the regulations among several agencies.
- c) the need for working closely with the private sector when developing regulations.
- d) the need for public consultations with stakeholders at every stage of the process of development of regulations and policies.

## First Application Exercise

### Instructions

- **You need to read the scenario below and complete the task.**
- **You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible**

Chapter 17 gives an overview of the requirements set by the Human Pathogens and Toxins Regulations. Your team forms the senior management of a research facility, which is based in Canada and specialises in research with Risk Group 3 human pathogens. (1) List all necessary actions that you need to take, in order to demonstrate that you are in compliance with the Regulations. (2) Elucidate what internal policy documents need to be developed, and how they would be implemented, monitored, and reviewed within the institution. (3) Prepare a draft of one internal policy document of your choice.



## Second Application Exercise

### Instructions

- **Chapter 17 gives an overview of the regulatory framework for biosafety and biosecurity in Canada.**
- **It also elucidates some of the key steps in the development and implementation of biosafety and biosecurity regulations, and the value of outreach efforts and stakeholder engagement.**
- **Read the scenario below, complete the task and report to the class.**

Your team represents the advisory committee of the national authority for biosafety and biosecurity in Country A. Your country is in the process of developing a national system for biosafety and biosecurity oversight, and has asked you to prepare **policy recommendations** on the structure and key components of the system, and how it would be implemented. As your country has limited experience with biosafety and biosecurity, you decide to look at how other countries have addressed the issue.

### Background information on Country A

Country A is a middle-income country with a rapidly growing biotechnology sector. It has ratified the key international agreements related to chemical and biological disarmament. Biosafety and biosecurity are new concepts, and there has only been limited engagement with them both at policy and grassroots level. There are two high-containment research facilities on the territory of Country A, where research with highly dangerous pathogens is conducted. The Government of Country A is interested in strengthening biosafety and biosecurity, and actively seeks to attract foreign international assistance. It has recently established a national authority, that is specifically tasked with oversight of biosafety and biosecurity.

### **Guiding Tips:**

- How will the system be structured, e.g. legal/voluntary controls etc.?
- What would be its key components?
- What type of research activities would be covered, e.g. industry, academia etc.?
- How would it be developed?
- What key stakeholders would be engaged?
- How would the system be implemented?
- What mechanisms would be in place to ensure compliance with the system's provisions?
- You can consult Chapters 14-17 of the Guide for the purposes of this task.

## Chapter 18: The Role of the Scientific Community in the Development and Strengthening of International Biosecurity Regulations

### Key Learning Objectives

- i. Understand how international governance mechanisms in the area of biotechnology impact on life science practice;
- ii. Develop an appreciation of how scientists can contribute to the development and implementation of biosecurity regulations.

### Individual/Team Readiness Assurance Test

#### Instructions

- Based on the information on the international governance of biotechnology provided in Chapter 18, write down the names of relevant international documents/agreements and respective international organisations/bodies, as specified for each category. The names of some agreements/organisations may be used more than once.
- Total number of points: 20 (each correct answer is worth 1 point).

Domain	International Organisation/Body	International Document/Agreement
Disarmament	1. 2. 3.	1. 2.
Biorisk Management	1. 2.	1. 2. 3. 4.
Disease Control	1.	1.

	2. 3.	2. 3.
Biodiversity	1.	1. 2.

## First Application Exercise

### Instructions

- **Based on the information provided in Chapter 18, you are asked to make a list, showing the key elements that are required for the implementation of biosecurity culture, from an international level to the level of the individual.**
- **You need to fill in the missing steps and provide a rationale for each of them, explaining their need and value.**
- **You need to nominate a spokesperson, who will speak for the team during the feedback time. This role should be shared around the team as much as possible.**

1. States Parties to the Biological and Toxin Weapons Convention (BTWC) agree on the value and urgency of fostering a culture of biological security and responsibility in the life sciences.

2.

3

4.

.....

Result: Individual staff at the laboratory adopt new practices, in order to maintain a culture of biological security.

## Second Application Exercise

### Instructions

- **Chapter 18 gives an overview of the processes that underpin international governance in the area of biotechnology.**
- **It also demonstrates both how international biotechnology regulations impact on scientific practice, and how scientists can contribute to the development of such regulations.**
- **Read the scenario below, complete the task and report to the class.**

You are a team of university science lecturers, who want to introduce their students to the topics of biological security and dual use, in order to raise awareness of the potential risks arising from novel advances. You decide to draft a proposal for how the existing curricula at your university can be changed, so that additional lectures and seminars on biological security can be added. As you prepare your proposal, you discover that, while the issue of biological security education has been discussed at international policy level, there are few guidelines on how awareness of the issue needs to be raised. Moreover, you also discover that there is little in the existing national policy on education in your country that requires life scientists to be aware of the potential risks of novel advances in biotechnology. You realise that the issue of education needs to be addressed not only at your university but nation-wide, and that a change in the current policy on life science education is required. As result, you decide to start a nation-wide campaign for a policy change. How would you plan your campaign and what action would you take to make it a success?

### **Guiding Tips:**

- Which international policy documents and agreements would you use to justify the need for education on biological security? You can refer to Appendix A of the Guide for ideas.
- Who are the stakeholders, that need to be consulted and possibly involved in the campaign, e.g. funding bodies, professional associations etc.?
- What you expect from the other stakeholders in terms of support for the campaign, e.g. how can they participate most effectively?
- Which government agencies would you consult and try to involve?
- What activities would do you envisage, in order to raise awareness of the value of your campaign and the need for it?
- Where would you seek advice on how best to organise your campaign, e.g. stakeholders within your country, collaborators abroad etc.?
- Would you try to promote your campaign internationally (e.g. at the BTWC Meetings etc.) and if yes, how would you do that?

## Chapter 19: Conclusion: Next Steps

### Using Team-Based Learning in Teaching Biological Security

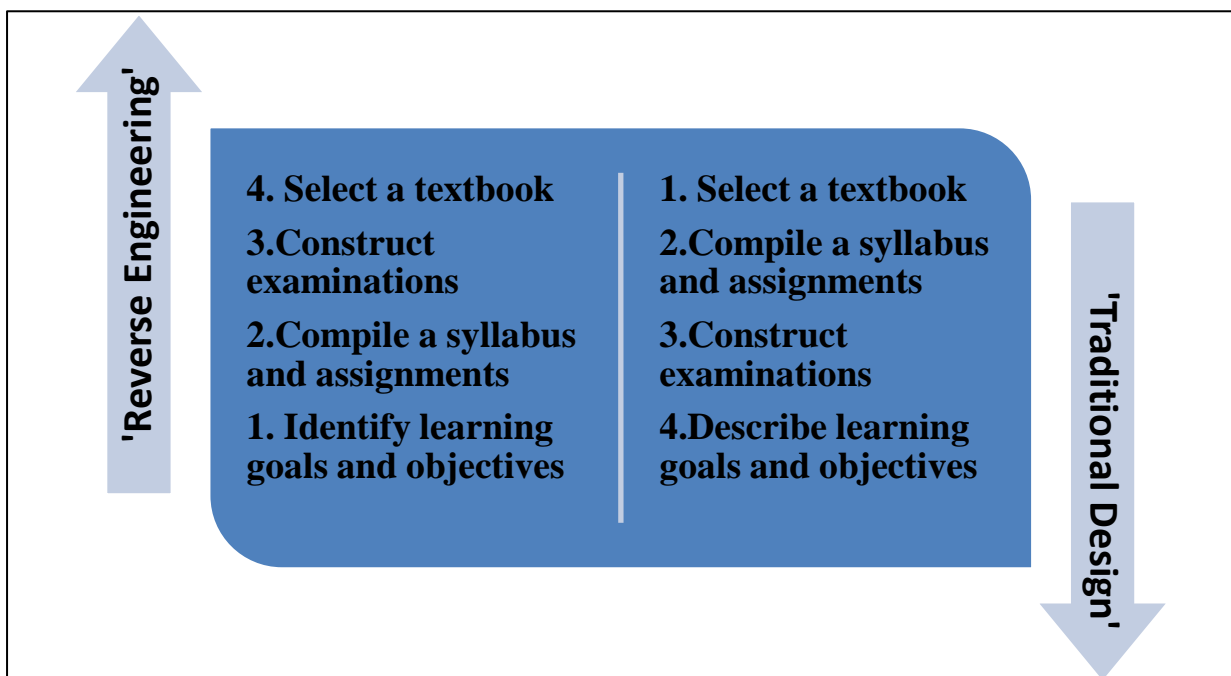
The present Handbook has sought to provide learners, instructors, and practitioners with insights into the Team-Based Learning format, and how it can be used in teaching biological security. The Handbook is indicative, and not prescriptive, and is aimed at offering guidance on how an active learning strategy with demonstrated effectiveness can be employed to engage those in the life sciences with the risks and concerns posed by cutting-edge biotechnology.

The Handbook has focused on a specific active learning strategy, Team-Based Learning. The choice of this particular active learning strategy is underpinned by several important considerations. First, the structure of the TBL format, reflected in the sequence of activities, allows for a two-tiered evaluation of learners' understanding of the teaching content. The iRATs and tRATs enable the instructor to assess learners' grasp of theory and factual subject-matter; the Application Exercises enable him or her to assess the extent to which learners critically engage with new concepts, and are capable of linking them to their everyday practice. Since the primary focus of all TBL tasks is **not** on choosing the single 'right' answer, but on being able to explain **why** a specific answer is considered 'right', learners are encouraged to move away from memorising concepts and develop an in-depth appreciation of, and ability to apply, the new concepts they encounter.

Second, the TBL format has proven to be an effective way of raising awareness of biological security. The iRATs and the tRATs make it possible for the instructor to establish the extent to which learners have grasped the content of individual chapters. The Appeal session, in turn, enables the learners to explain the reasoning behind their choice of individual answers, thus allowing them to take ownership of their learning. Likewise, the Application exercises seek to further deepen learners' critical thinking with regard to biological security, by providing them with a space for debate and discussion. The practical tasks in the form of scenarios allow the learners to assume roles, and thus approach complex problems from a different perspective, one that they may not have been previously familiar with, or that they may not necessarily share. The goal in this case is to encourage the learners to analyse biological security issues from a particular standpoint, by applying the new concepts to which they have been introduced, in a novel and creative way.

An underlying feature of the TBL format is the fact that it is modelled on the principle of ‘reverse engineering’, or ‘backward design’.<sup>11</sup> In effect, the principle of reverse engineering, when applied to course development, refers to the process whereby the identification of learning objectives and assessment modes comes first. The compilation of a syllabus, the choice of relevant training resources, and the preparation of exam questions, are all subject to the particular learning goals set for the course/seminar. Figure 19.1 illustrates how the principle of ‘reverse engineering’ differs from other approaches to course-development, that do not make use of active learning.

**Figure 19.1: ‘Reverse Engineering’ vs. ‘Traditional Design’**

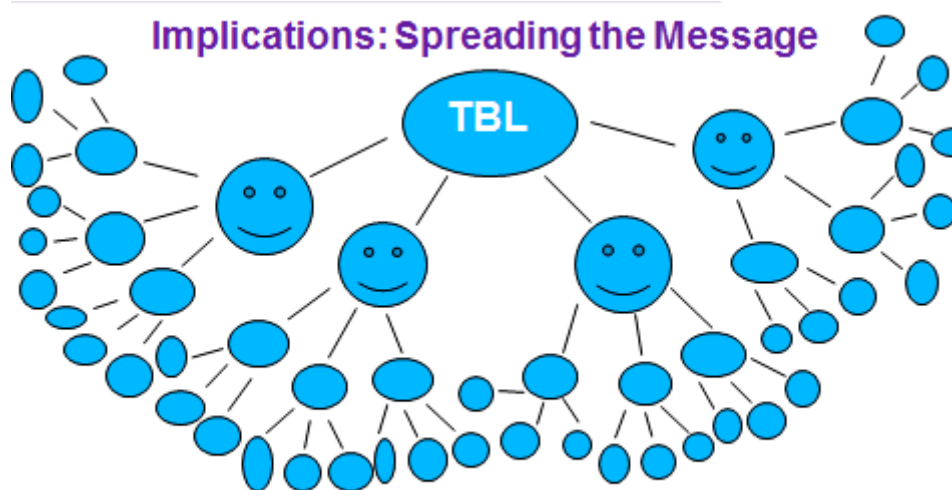


Each chapter of the Handbook has been designed following the principle of ‘reverse engineering’. For each chapter of the Guide, a key concept has been identified. The learning objectives suggested at the beginning of each chapter of the Handbook are intended to guide both the instructor and the learners, with regard to what goals each set of activities is directed at. The corresponding exercises then seek to assist the learners in achieving the proposed learning objectives. As a result, it is possible both for the instructor and the learners to

determine the extent to which the learning objectives have been met; identify any remaining gaps in knowledge and/or understanding; and evaluate the effectiveness of the session.

Third, the TBL format constitutes an easy-to-replicate, user-friendly train-the-trainer methodology. Given its clear structure and defined sequence of activities, the format is relatively easy to use in different educational contexts with different audiences. The availability of open-source material, specifically designed to engage educators with biological security, makes it possible for interested individuals to use and adapt the information contained in the Guide and the Handbook to their own needs and circumstances. Because of its structure, the TBL format is easy to replicate, once an individual has been exposed to it. Moreover, as the TBL format can be used to train a large number of people at once, it can be regarded as an excellent train-the-trainer strategy, particularly in the context of continued professional development courses among life science professionals (see Figure 19.1).

**Figure 19.1: TBL as a train-the-trainer approach**



The present Handbook has aimed to combine training content in biological security with an effective and efficient active learning approach – Team-Based Learning. The material contained herein has been intended to facilitate engagement among those in the life sciences with issues of biological security, and to offer guiding tools in the process of developing



relevant curricula both for academic and professional training purposes. As such, the Handbook can serve as a starting point for fostering educational networks for data sharing, and exchange of best practices and lessons learned.

## References

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<sup>1</sup> Simon Whitby et al. (ed.) *Preventing Biological Threats: What You Can Do: A Guide to Biological Security Issues and How to Address Them*, Bradford: University of Bradford, 2015.

<sup>2</sup> Ibid.

<sup>3</sup> See, for example, National Research Council, *How People Learn: Brain, Mind, Experience, and School* (Washington DC: National Academies Press, 2000); National Research Council, *Developing Capacities for Teaching Responsible Science in the MENA Region: Refashioning Scientific Dialogue* (Washington DC: National Academies Press, 2013).

<sup>4</sup> See National Research Council, *Research in the Life Sciences with Dual-Use Potential: An International Faculty Development Project on Education about the Responsible Conduct of Science* (Washington DC, National Academies Press, 2012), p.5.

<sup>5</sup> US National Academies of Sciences, *Insights from the Science of Learning for Education*, available at <http://nas-sites.org/biosecurity/current-projects/insights-from-the-science-of-learning-for-education/> (accessed 30 November 2015).

<sup>6</sup> For an overview of the Team-Based Learning format, see Centre for Instructional Support, University of British Columbia, *What Is TBL?*, available at [https://www.byui.edu/Documents/instructional\\_development/Larry%20Michaelsen/TBL%20why%20and%20how.pdf](https://www.byui.edu/Documents/instructional_development/Larry%20Michaelsen/TBL%20why%20and%20how.pdf) (accessed 30 November 2015).

<sup>7</sup> Further information on the seminars conducted as part of the EU CBRN Centres of Excellence Project 18 is available at <http://landaunetwork.org/index.php/category/project-18/> (accessed 30 November 2015).

<sup>8</sup> Additional information on the formation of teams, and other issues, related to the elements of TBL, see *Team Formation for TBL*, available at <http://www.teambasedlearning.org/page-1032336> (accessed 30 November 2015). See also Larry Michaelsen et al. *Team-Based learning: Small Group Learning's Next Big Step: New Directions for Teaching and Learning*, No.116 (Jossey-Bass, 2009).

<sup>9</sup> For an overview of Bloom's Taxonomy of Learning, see <http://www.learningandteaching.info/learning/bloomtax.htm> (accessed 30 November 2015).

<sup>10</sup> For information on Poll Everywhere and how to set up a multiple-choice questions quiz, see <https://www.polleverywhere.com/> (accessed 13 December 2015). I am indebted to Susan Caskey of Sandia National Laboratories for bringing Poll Everywhere to my attention.

<sup>11</sup> Committee on Developing a Framework for an International Faculty Development Project on Education About Research in the Life Sciences with Dual Use Potential, *Developing Capacities for Teaching Responsible Science in the MENA Region: Refashioning Scientific Dialogue* (Washington DC: National Academies Press, 2013), available at [http://nap.edu/catalog.php?record\\_id=18356](http://nap.edu/catalog.php?record_id=18356) (accessed 2 December 2015).