Strengthening the Biological Weapons Convention

Briefing Paper No 4 (Third Series)

Full and Effective Biological Risk Management

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FULL AND EFFECTIVE BIOLOGICAL RISK MANAGEMENT

by Simon Whitby[†] and Graham S. Pearson[*]

Introduction

1. The letter[1] of the Chairman of the Meeting of Experts and the Meeting of States Parties of the Biological and Toxin Weapons Convention (BTWC) in 2012 dated 1 June 2012 and the subsequent letter[2] of 21 June 2012 proposes that the Standing Agenda item on *Review of developments in the field of science and technology related to the Convention* will in 2012 *inter alia* address the following topic:

> *(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;*

2. This Briefing Paper examines what should be addressed in considering biological risk management and focuses on how to strengthen the Convention through achieving full and effective biosecurity in the life sciences.

Terminology

3. It is important in considering how to achieve full and effective biological risk management in the life sciences to first examine the terminology that is in use and its relevance or otherwise. Biological risk management, or biorisk management, consists of three components: a. biosafety, b. biosecurity and c. ethics. It also needs to be recognized that these can be **restricted** to consideration of activities within a laboratory or can be **extended** to consideration of wider activities. This Briefing Paper focuses on the **broader** consideration thereby addressing how to achieve full and effective biological risk management.

4. ***Biosafety.*** According to the World Health Organisation (WHO) *Biosafety Manual*[3] issued in 2004 the term "*laboratory biosafety*" is:

> *used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.*

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[1] United Nations, Meeting of the States Parties to the Convention on the Prohibition of Biological and Toxin Weapons Convention, Geneva, *Biological Weapons Convention Meeting of Experts 16 – 20 July 2012,* Letter from the Chairman, 1 June 2012.

[2] United Nations, Meeting of the States Parties to the Convention on the Prohibition of Biological and Toxin Weapons Convention, Geneva, *Biological Weapons Convention Meeting of Experts 16 – 20 July 2012,* Letter from the Chairman, 21 June 2012.

[3] World Health Organization, *Laboratory Biosafety Manual*, Third Edition, 2004. Available at: www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

It is possible to think of laboratory biosafety in terms of safe laboratory"*practices, procedures, actions and habits that protect the people working with biological materials"*. Indeed, a combination of the routine application of good laboratory practice with personal protective equipment and properly trained personnel contributes to a comprehensive, integrated and sustainable laboratory "*biosafety*" culture in many countries around the world today.

5. ***Biosecurity.*** The World Health Organisation (WHO) *Biosafety Manual*[4] issued in 2004 also states that the term "*laboratory biosecurity*" is used to refer to:

> *institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.*

However, the use of the word "*biosecurity*" can be interpreted in different ways. The following three examples show how the term *biosecurity* can mean different things to different people.

6. First, as the WHO in September 2006 noted in its *Laboratory Biosecurity Guidance*[5] issued as part of its approach to *Biorisk Management*:

> *The term "biosecurity" has been used in different contexts and has acquired different meanings (veterinary health, ecology, agriculture, food supply, arms control, public health, etc.) for people with different backgrounds.*

Furthermore, for example, in the context of *food supply*, the WHO *Laboratory Biosecurity Guidance* notes that:

> *"Biosecurity" refers to the policies and measures taken for protecting a nation's food supply and agricultural resources from both accidental contamination and deliberate attacks of bioterrorism. Bioterrorism might include such deliberate acts as introducing pests intended to kill food crops; spreading a virulent disease among animal production facilities; and poisoning water, food and blood supplies.*

Second, the WHO *Laboratory Biosecurity Guidance* also notes that

> *the term "biosecurity" is inconsistently translated into various languages.*

Third, whilst earlier editions of the WHO *Laboratory Biosecurity Guidance* advanced a definition of "*biosecurity*" that focused on securing valuable biological material (VBM) within the confines of the laboratory and on mitigation of its *loss, theft, misuse, diversion or intentional release*, the Third Edition of the *Laboratory Biosecurity Guidance* in 2006 addresses a broader consideration of biosecurity beyond laboratory doors. The extension of the concept is shown below in regard to broadening the scope and then in considerations of misuse/dual-use.

7. The WHO *Laboratory Biosecurity Guidance*[6] in 2006 broadens the scope by stating that:

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[4] World Health Organization, *Laboratory Biosafety Manual*, Third Edition, 2004. Available at: www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

[5] World Health Organization, Biorisk Management, *Laboratory Biosecurity Guidance*, WHO/CDS/EPR/2006.6, September 2006. Available at www.who.int/csr/resources/publications/.../WHO_CDS_EPR_2006_6.pdf

> *the scope of laboratory biosecurity is broadened by addressing the safekeeping of all* ***valuable biological materials*** *(VBM), including not only pathogens and toxins, but also scientifically, historically and economically important biological materials such as collections and reference strains, pathogens and toxins, vaccines and other pharmaceutical products, food products, GMOs, nonpathogenic microorganisms, extraterrestrial samples, cellular components and genetic elements. This is done in order to raise awareness of the need to secure collections of VBM for many reasons, including: for the sake of biology, to preserve biological diversity and endangered species, to perform microbiological studies and better understand the living world and the science behind it; to safeguard resources from which new drugs, vaccines and life-saving materials may be developed, for historical reasons, and to advance the state of knowledge.*

8. In addition, the WHO *Laboratory Biosecurity Guidance* also addresses the potential for misuse and/or dual-use by stating that:

> *Bioscience research has contributed to the progress of humanity through the development of new vaccines and drugs, and to an improved understanding of human health. However, bioscience has the potential to harm if misused, i.e. the biosciences are inherently dual-use. Although the vast majority of applications of bioscience have been used for good and peaceful purposes, the potential for harmful misuse may suggest the need for specific protective measures for laboratory facilities, the VBM they contain, the work performed, and the staff involved.*

Although the WHO uses the word *research* in this respect, it would be more accurate and comprehensive to use the term *activities* as in consideration of misuse/dual-use the focus needs to be on *activities* in the life sciences – whatever their nature and regardless of whether they be described as research, exploratory development or development. The terms *research, exploratory development* and *development* are used differently from country to country. Research may be interpreted more narrowly in some countries than in others. This makes the case for replacing *research* by the word *activities* all the stronger.

9. Thus it is possible to consider biorisk management in both restricted and extended forms. In a restricted appreciation of biorisk management, *laboratory biosafety* and *laboratory biosecurity* share the common goals of efficient and effective biological containment through the implementation of best practice although the risks they seek to mitigate are different with *biosafety* maximising safety and minimizing the risk of accidental release, and *biosecurity* minimizing the risk of *loss, theft, misuse, diversion or intentional release*. Thus, the combined objectives of *laboratory biosafety* and *laboratory biosecurity* are described in the WHO *Laboratory Biosecurity Guidance* as follows:

> *Laboratory biosecurity may be addressed through the coordination of administrative, regulatory and physical security procedures and practices implemented in a working environment that utilizes good biosafety practices, and where responsibilities and accountabilities are clearly defined. Biosafety and laboratory biosecurity are complementary.*

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[6] World Health Organization, Biorisk Management, *Laboratory Biosecurity Guidance*, WHO/CDS/EPR/2006.6, September 2006. Available at www.who.int/csr/resources/publications/.../WHO_CDS_EPR_2006_6.pdf

The WHO *Laboratory Biosecurity Guidance* also notes that:

> *The systematic use of appropriate biosafety principles and practices reduces the risk of accidental exposure and paves the way for reducing the risks of VBM* [valuable biological materials] *loss, theft or misuse caused by poor management or poor accountability and protection. Laboratory biosecurity should be built upon a firm foundation of good laboratory biosafety.*

10. The extended appreciation of biorisk management, however, recognises a concept of biosecurity that includes *policies and measures* to mitigate against dual-use bioscience and its potential for misuse against humans, animals and crops.

11. ***Ethics.*** The third component of biorisk management is ethics (including professional integrity in life science activities and practice). Although some codes of ethics make specific reference to the misuse of the life sciences – such as the Code of Ethics[7] of the International Union of Biochemistry and Molecular Biology adopted in December 2005 which states:

> *7. They will not engage knowingly in research that is intended for the production of agents of biological warfare or bioterrorism, nor promote such agents.*

– most codes do not include specific reference to the misuse of the life sciences. For example, although the Universal Declaration on Bioethics and Human Rights[8] adopted in October 2005 notes in its introductory paragraphs that:

> ***Reflecting*** *on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,*
>
> ***Recognizing*** *that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,*

and goes on to include as one of its principles in Article 4:

> ***Article 4 – Benefit and harm***
>
> *In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.*

[7] International Union of Biochemistry and Molecular Biology, *Code of Ethics of the International Union of Biochemistry and Molecular Biology*, Approved by the Executive Committee of IUBMB, December 2005. Available at http://www.iubmb.org/index.php?id=155

[8] United Nations Educational, Scientific and Cultural Organization, (UNESCO), Universal Declaration on Bioethics and Human Rights, adopted by acclamation by the General Conference of UNESCO, October 2005. Available at unesdoc.unesco.org/images/0014/001461/146180e.pdf

it does not include the Biological and Toxin Weapons Convention in its listing of various international conventions such as the United Nations Convention on Biological Diversity of 5 June 1992, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by FAO. There is, however, a general reference to *other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).*

12. Ethics is relevant to biorisk management in the context of the laboratory. But it is also of relevance in biorisk management because it extends biosecurity concerns beyond the laboratory door. According to the WHO *Laboratory Biosecurity Guidance* the term *bioethics* is:

> *The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research.*

Thus one of the core objectives of the WHO *Laboratory Biosecurity Guidance* is:

> *to expand the laboratory biosecurity concepts introduced in the WHO Biosafety Guidance and to strike a balance between the long-known biosafety procedures and practices described … and the more recently introduced and broader biosecurity concepts. It further introduces the overarching "biorisk management" approach that has resulted from careful thinking, comprehensive study of prevailing practices and recommendations, review of international norms and standards, and relevant ethical considerations*

13. An important more recent development has been the publication by the World Health Organization in 2010 of a guidance document[9] entitled *Responsible life sciences research for global health security.* This document recognizes, and indeed mentions the Biological and Toxin Weapons Convention, although it is focused on a public-health objective. Its purpose is stated to be:

> *The purpose of this guidance is to inform Member States about the risks posed by accidents or the deliberate misuse of life sciences research and to propose measures to minimize them within the context of promoting and harnessing the power of the life sciences to improve health for all people.*

Although this document unfortunately uses the word *research* in its title and widely through the guidance, it should be recognized (as expounded in paragraph 8 above) that its recommendations are applicable to **activities** in the life sciences and these should be supported.

[9] World Health Organization, *Responsible life sciences research for global health security*, A guidance document, 2010. Available at whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf

Biorisk Management

14. The WHO *Laboratory Biosecurity Guidance* offers an alternative approach to application and compliance when compared to regulation or legislation. It does not set out universally agreed principles and practices; rather the guidance articulates a *goal-setting* approach that describes:

> *performance expectations for facilities, and placing the responsibility on single facilities to demonstrate that appropriate and valid biorisk minimization measures have been established.*

The Biorisk Management approach is therefore neither prescriptive nor is compliance with it mandatory, rather it:

> *describes recommendations and performance expectations, placing responsibility on national authorities and facility managers to demonstrate that appropriate and reasoned biorisk minimization procedures have been established and will be implemented. These recommendations do not call for compliance with a set of requirements, but rather help to identify and set goals to be achieved. This approach allows countries and facility managers to define and choose appropriate systems and controls to ensure that the biorisk management goals that have been identified are reached. It allows institutions to adapt their laboratory biosecurity plans to their particular situation.*

15. Thus in regard to the three core components of the Biorisk Management approach – biosafety, biosecurity, and ethics - the WHO *Laboratory Biosecurity Guidance* argues that:

> *National authorities and laboratory managers should be able to provide for a legislative and/or regulatory framework defining legitimate and ethical research projects and keep an oversight on laboratory activities and personnel. Systems and controls should be in place to avoid illegitimate or unethical research. Researchers, laboratory workers and biosafety and laboratory biosecurity managers should communicate and collaborate, and strive to find the correct ethical balance for the activities performed.*

Although the WHO *Guidance* uses *research* in the above, it is evident that this approach should be adopted for all *activities* in the life sciences.

16. The WHO *Guidance* goes on to identifies tasks and responsibilities for efficient and effective biorisk management. These consist of the following seven components:

> *1. Identify VBM that require protection on the basis of regularly performed biorisk assessments.*
> *2. Establish clear guidance, roles, responsibilities and authorities for those who work with or have access to VBM and to the facilities that contain them.*
> *3. Promote a culture of awareness, shared sense of responsibility, ethics, and respect of codes of conduct within the international life science community.*
> *4. Develop policies that do not hinder the efficient sharing of reference materials and scientific data, clinical and epidemiological specimens and related information, and that do not impede the conduct of legitimate research.*

5. Strengthen collaboration between the scientific, technical and security sectors.
6. Provide appropriate training to employees of laboratory facilities.
7. Strengthen emergency response and recovery plans on the assumption that biorisk management systems can only minimize, but never really eliminate, every conceivable threat.

Once again in the fourth component above, the word *activities* should replace the word *research* for the reasons expounded in paragraph 8 above.

17. Responsibilities are also assigned to the wide range of stakeholders involved in the implementation of a biorisk management programme within a facility. Working under the ultimate responsibility of a facility director stakeholders include: principal investigators, biosafety and biosecurity managers, biosafety officers, managers, as well as institutional biosafety review committees, laboratory staff, maintenance and security personnel with different roles being assigned to different stakeholders. As argued in the WHO *Guidance*:

> *A possible approach to minimizing the dual-use of materials and equipment within a facility is to give a competent biosafety and laboratory biosecurity manager the responsibility for the scientific programme, in consultation with the principal investigator, for approving research projects and authorizing experiments, in compliance with national requirements and bioethical considerations* [with roles being assigned also to the] *institutional biosafety committee and …research manager.*

18. Thus, according to the WHO *Laboratory Biosecurity Guidance*, a *comprehensive laboratory biosecurity programme* involves the following:

1. identification of VBM,
2. associated agent-based microbiological risk assessment and laboratory biosecurity risk assessment,
3. bioethical and scientific analysis of research projects before they are authorized,
4. allocation of responsibilities and authorities among staff and facility managers,
5. communication between parties involved,
6. development of and training on emergency plans; and,
7. tailored biosecurity training for employees of the facility and for external first-responders.

19. Overall, in setting out tasks and responsibilities in the areas of biosafety, biosecurity and ethics, the WHO *Laboratory Biosecurity Guidance* has sought to address:

> *VBMs and the growing advances in life sciences and related technologies that are likely to alter the spectrum of current and future biorisks, presenting ways to identify, prevent and minimize them.*

20. *Appreciation.* The approach advocated by the WHO to biorisk management is, thus, not prescriptive in that it does not require mandatory compliance with universally agreed principles and practices. Rather it makes recommendations, is goal-setting and aspirational, setting performance expectations upon laboratory facilities whilst allowing flexibility in regard to the implementation of biorisk management programmes to suit local contexts. Such expectations also extend to the area of training. According to the WHO *Laboratory Biosecurity Guidance*:

Laboratory biosecurity training, complementary to laboratory biosafety training and commensurate with the roles, responsibilities and authorities of staff, should be provided to all those working at a facility, including maintenance and cleaning personnel, and to external first-responders and responsible staff involved in ensuring the security of the laboratory facility. Such training should help understand the need for protection of VBM and equipment and the rationale for the laboratory biosecurity measures adopted, and should include a review of relevant national policies and institution-specific procedures.…Training should also provide guidance on the implementation of codes of conduct and should help laboratory workers understand and discuss ethical issues…. Training should not be a one-time event. Training should be offered regularly and taken recurrently.

Standards, Competency and Training in Biorisk Management

21. ***Standards.*** The European Committee for Standardisation (CEN) Workshop Agreements process has provided a mechanism in which stakeholders can bring their standardization and specification requirements and develop a result by consensus, validated in an open process. This was done for the *Laboratory Biorisk Management* (CWA 15793)[10] agreement which was agreed by consensus[11] by a wide range of stakeholders in December 2007 and was published in January 2008 and reissued in September 2011.

22. The scope of this CEN *Laboratory Biorisk Management* (CWA 15793) agreement is to:

…set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.

This CWA will enable organizations to:

a) establish and maintain a biorisk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;
b) provide assurance that the requirements are in place and implemented effectively;
c) seek and achieve certification or verification of the biorisk management system by an independent third party;
d) provide a framework that can be used as the basis for training and raising awareness of laboratory biosafety and laboratory biosecurity guidelines and best practices within the scientific community.

23. This CEN agreement goes on to set out:

[10] CEN Workshop Agreement, *Laboratory biorisk management*, CWA 15793:2011, September 2011. Available at ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf

[11] Whilst CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom, this CEN agreement included contributions from 76 participants from the following countries: Argentina, Australia, Belgium, Canada, China, Denmark, Germany, Ghana, Hong Kong, Hungary, Ireland, Japan, Kazakhstan, Kyrgyzstan, Latvia, the Netherlands, Norway, Russia, Singapore, Spain, Sweden, Switzerland, the United Kingdom and the United States. The WHO also participated in the Workshop. There was also a public comment phase that brought comments from an additional 33 stakeholders from Argentina, Canada, Europe, Russia, Taiwan and the United States.

Keys to a successful biorisk management system

Some of the key factors in establishing and implementing a successful biorisk management system include:

- *Commitment by top management:*

  - *providing adequate resources, prioritization and communication of biosafety and biosecurity policy;*
  - *integrating of biorisk management throughout the organization;*
  - *identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.*

- *Focus on continual improvement:*

  - *making continual improvement an objective for every individual in the organization;*
  - *using periodic assessment against established risk-criteria to identify areas for potential improvement;*
  - *continually improving the effectiveness and efficiency of processes;*
  - *promoting prevention activities;*
  - *providing personnel in the organization with appropriate education and training including the methods and tools of continual improvement;*
  - *establishing measures and goals for improvement;*
  - *recognizing improvement.*

24. *Application.* Although the CEN *Laboratory Biorisk Management* (CWA 15793) agreement is issued as an official document by the European Standards Agency, application of this agreement is voluntary unless directives, legislation or regulation declares otherwise. As noted by the German Committee on Biological Agents[12], an example of where application of this agreement is required can be found in the CBRN Action Plan[13] adopted by the Council of the European Union on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union which in Action B.4 calls on the Commission and the Member States to take steps so that:

> *facilities possessing substances on the EU list of high risk biological agents and toxins consider as appropriate the implementation of the CEN25 Workshop Agreement (CWA 15793), WHO Laboratory Biosecurity Guidance or their national equivalent standards - unless equal or more stringent national regulations have to be considered;*

[12] Ausschuss für Biologische Arbeitsstoffe (ABAS), *Position Paper of the Committee for Biological Agents on the Laboratory Biorisk Management Standard (CWA 15793:2008)*. Decisions 02/2010 and 26/2010 of the ABAS. Available at: http://www.baua.de/en/Topics-from-A-to-Z/Biological-Agents/Laboratory-Biorisk.html

[13] Council of the European Union, *COUNCIL CONCLUSIONS on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union - an EU CBRN Action Plan*, 15505/1/09 REV 1, 12 November 2009. Available at http://register.consilium.europa.eu/pdf/en/09/st15/st15505-re01.en09.pdf

25. The CEN *Laboratory Biorisk Management* (CWA 15793) agreement states that:

> *The requirements of this agreement are generic and are intended to be applicable to all organizations handling biological agents and/or toxins, regardless of type, size and biological agents handled. This agreement takes a risk-based approach but it does not employ biological agent risk classification or laboratory safety/containment levels, although such approaches can be entirely compatible with this agreement.*
>
> *Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any programme. Where any part of this agreement is in conflict with any legal requirement, the conflicting part of the agreement may be eligible for exemption if the legal requirement meets or exceeds the intent of this agreement.*

26. ***Competency***. Meetings to address professional competence in biosafety started in 2006 and led to a series of Workshops on Biosafety Professional (BSP) Competence (CWA 16335) held in 2009 and 2010 proposed by the European Biosafety Association (EBSA). This has led to the publication of the *Biosafety Professional Competence Agreement* (CWA 16335)[14] in 2011.

27. The *Laboratory Biorisk Management* (CWA 15793) agreement and the *Biosafety Professional Competence Agreement* (CWA 16335) are distinct but related agreements. The adopted Business Plan[15] for a *CEN Workshop Agreement for Biosafety Professional (BSP) Competence* issued in June 2010 states that:

> *CWA 15793* [the Laboratory Biorisk Management agreement] *recognizes a key role for the biosafety professional in a laboratory biosafety and biosecurity management programme. While CWA 15793* [the Laboratory Biorisk Management agreement] *defines the role of the BSP* [Biosafety Professional] *in general terms, the present initiative* [for a Biosafety Professional Competence Agreement] *complements the CWA by clearly defining the role profile, the tasks and competency requirements for the BSP* [Biosafety Professional], *as well as corresponding training curriculum for BSP* [Biosafety Professional], *setting a framework for establishing training programmes.*

28. Although CEN Workshop Agreement 53[16] cited here formed the basis for subsequent agreement in the Biosafety Professional Competence Agreement (CWA 16335), it established competence in both biosafety and biosecurity by defining the role profile, the

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[14] CEN Workshop Agreement, *Biosafety Professional Competence*, CWA 16335:2011, September 2011. Available for purchase at www.nen.nl/web/Normshop/Norm/CWA-163352011-en.htm The draft CEN Workshop Agreement, *Biosafety Professional Competence*, prCWA 53:2010 (E), 2010-11 is available at http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Documents/WS%2053prCWA%2053.pdf

[15] European Committee for Standardization (CEN), *Business Plan for a "CEN Workshop Agreement for Biosafety Professional (BSP) Competence"*, CEN/WS 53, Business Plan version 1.18, 16 June 2010. Available at http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Documents/AdoptedBusinessPlan.pdf

[16] European Committee for Standardization (CEN), Draft CEN Workshop Agreement, *Biosafety Professional Competence*, prCWA 53:2010 (E), 2010-11. Available at http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Documents/WS%2053prCWA%2053.pdf

tasks and the competency requirements of the BSP with reference to the Laboratory Biorisk Management (CWA 15793) agreement. A BSP curriculum, a framework for training and certification are also proposed in this guidance with potential stakeholders identified as:

> *all organisations, regardless of type or size, where the management has identified the need to appoint a biosafety professional.*

In general terms the CEN Workshop Agreement 16335 sets out a role for the biosafety professional as follows:

> *an individual who has a broad range of competences and abilities to advise management and personnel on biosafety- and biosecurity-related issues and to manage and support the development and implementation of relevant management programmes or systems. ….*
>
> *The biosafety professional should assist management to develop a biosafety and biosecurity policy appropriate to the nature and scale of the risk associated with the organisation and the work to be performed. The policy should set the biosafety and biosecurity goals and objectives for the organization.*
>
> *The biosafety professional should, together with the senior management, project leaders and technical services personnel, develop a biorisk management programme appropriate to the nature and scale of the work with hazardous biological material planned and performed by the organization.*

29. *Application.* In terms of its application, CEN Workshop Agreement 16335 states that:

> *The CWA is a framework applicable internationally. It does not have the force of regulation.*
>
> *This CEN Workshop Agreement (CWA) describes competence areas of a biosafety professional. International, national or regional regulations or directives take precedence over this CWA.*

Additionally, it is also noted that the application of the agreement is restricted to the laboratory context and is thus somewhat out of step with *the Laboratory Biorisk Management* (CWA 15793) agreement which sought to broaden the concept of biosecurity beyond the laboratory doors.

30. Thus the CEN *Biosafety Professional Competence Agreement* (CWA 16335) states as follows that:

> *This document is intended to provide a framework for those who work in the biosafety and biosecurity fields to evaluate their competence as a professional and to identify areas for development. In the context of this document biosecurity is restricted to laboratory biosecurity.*

31. Although there is considerable scope for overlap with existing biosafety job specifications that are set out across a range of national professional contexts, the *model role profile, model tasks* and *model training specifications* contained in the *Biosafety Professional Competence*

Agreement comprise extensive and detailed requirements for competence. Indeed some tasks indicate requirements that appear to be outside of those traditionally associated with the role of a biosafety professional such as, for example, *ergonomics, waste management and transport*[17].

32. Both *core* and *specialised* competencies are specified in CEN agreement 35. The former are listed in 25 sub-clauses and range from *general principles of microbiology, biochemistry and cell biology* through to *bioethics* and are those that all biosafety professionals should be able to fulfil, whilst the latter are defined as *specialist* competencies to be fulfilled by the biosafety professional in *complex and/or higher risk environments*.

33. ***Training.*** In regard to training the *Biosafety Professional Competence Agreement* (CWA 16335) notes:

> *This CWA provides in informative annexes a model role profile and model tasks of a biosafety professional in an organization; these help to define competence requirements. It also provides model training specifications for reaching competence.*

and goes on to add that:

> *All biosafety professionals shall be able to demonstrate the core competences listed below. The competences listed below are required to carry out the tasks described in informative Annex B – Tasks of the biosafety professional and these competences can be acquired in part by training programmes such as those set out in informative Annex C – Training specifications. An overview of the relationship between competences, tasks and training specifications are presented in informative Annex E*

Whilst biorisk management-related competence and certification of both individuals and institutions is to be welcomed, training courses will be needed if a sustainable capability is to be created for this area of expertise on a world-wide basis; and certification and audit bodies or institutions will need to be established in order to verify both competence and compliance.

34. Currently training courses in biorisk management are few in number. One excellent example is the annual Laboratory Biorisk Management Workshop run by Stefan Wagener at the National Microbiology Laboratory, Public Health Agency of Canada, Winnipeg, Manitoba, Canada.

35. This course is run by the following organisations and has the following objectives[18]:

> *The Public Health Agency of Canada's National Microbiology Laboratory Office of Biorisk Management, together with Sandia National Laboratories and the International Centre for Infectious Diseases, present a five day intensive workshop focusing on how to implement a bioethics, biosafety and biosecurity management system centered on the new international CEN Workshop Agreement (CWA) 15793:2008 and the WHO*

[17] Ausschuss für Biologische Arbeitsstoffe (ABAS), Position paper of the Committee for Biological Agents (ABAS) concerning CWA 16335:2011 "*Biosafety professional competence*" (formerly CEN Workshop 53), Decision 28/2011 of the ABAS. Available at http://www.baua.de/de/Themen-von-A-Z/Biologische-Arbeitsstoffe/ABAS/aus-dem-ABAS/Biosicherheit.html

[18] ICID International Centre for Infectious Diseases, Winnipeg, Manitoba, Canada: 4th annual *Laboratory Biorisk Management* Workshop, 30 April – 4 May 2012. See http://www.biosafety.ca/bmsl/home.html

"Responsible life sciences research for global health security" Guidance Document.

The target audience, proposed topics, as well as the learning outcomes associated with this course are as follows:

> *This workshop is specifically designed for today's laboratory managers and directors, scientists, biosafety professionals and safety managers, research and laboratory staff.*
>
> *Proposed topics include:*
>
> - *Laboratory Biosafety and Biosecurity Management System*
> - *International Laboratory Biorisk Management Agreement CWA 15793:2011*
> - *Responsible life science research*
> - *Audits/Certification/Accreditation*
> - *Risk Assessment Process and Methodology*
> - *Process Mapping*
>
> *After successfully completing this five-day workshop our participants will recognize:*
>
> - *Management system principles*
> - *Application and use of the CWA 15793:2008*
> - *Project management tools and strategies*
> - *Dual-use, bioethics concepts*
>
> *In addition, participants will be able to (key learning outcomes):*
>
> - *Explain the three key components of a Biorisk Management System*
> - *Develop a biorisk assessment method for their own lab and use the newly developed BioRam tool (Sandia Natl. Labs) to assess risks associated with biological materials in the laboratory*
> - *Perform audits and communicate audit results*
> - *Develop a strategy for the implementation of a biorisk management system in a laboratory*
> - *Develop and use Level 1-3 Process maps (Flowcharts)*
> - *Develop a dual use, bioethics policy and review criteria*

36. In regard to competence, compliance and audit, a recent and important initiative initiated by the International Federation of Biosafety Associations is particularly relevant[19]:

> *the International Federation of Biosafety Associations (IFBA) has recently launched a project on Ensuring Quality Biorisk Management through Certification of Professionals. The chief goal of the project is to 'create a certification scheme that establishes levels of technical competency in several disciplines' including bioethics/biosecurity. Qualifications will be granted once individuals have successfully completed 'certified training programmes delivered by certified trainers' and have demonstrated achievement of the required teaching objectives and learning outcomes.*

[19] Simon Whitby and Tatyana Novossiolova, *Biosecurity Training and Competence: Preserving Life Science Research Integrity and Ensuring Compliance* (Conference Paper), Bradford Disarmament Research Centre: Responsible Conduct of Research for Scientists and Engineers – Twin International Meeting, 9 – 11 July 2012, Norcroft Conference Centre, University of Bradford. See: http://www.brad.ac.uk/bioethics

Biosafety, Biosecurity, Biorisk Management, and the BTWC

37. It is now appropriate to recall how the topics of biological risk management and biosafety and biosecurity have been addressed hitherto by the States Parties to the BTWC.

The BTWC Intersessional Programme and the Seventh Review Conference

38. The Intersessional Programme between the Sixth and Seventh Review Conferences in 2008 considered:

> *(c) National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins.*
>
> *(d) Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bioscience and bio-technology research with the potential of use for purposes prohibited by the Convention.*

39. The report[20] of the Meeting of States Parties in 2008 noted:

> *19. With respect to both topics of the Meeting, States Parties recognised the need for proportional measures, for carefully assessing risks, for balancing security concerns against the need to avoid hampering the peaceful development of biological science and technology, and for taking national and local circumstances into account.*

The report goes on to note that the States Parties agreed on the value of:

> *21. Recognising that biosafety and biosecurity measures contribute to preventing the development, acquisition or use of biological and toxin weapons and are an appropriate means of implementing the Convention, States Parties agreed on the value of:*
>
> > *(i) National authorities defining and implementing biosafety and biosecurity concepts in accordance with relevant national laws, regulations and policies, consistent with the provisions of the Convention and taking advantage of relevant guidance and standards, such as those produced by the FAO, OIE and WHO;*
> >
> > *(ii) National governments taking the leading role, including by nominating a lead agency (or focal point), specifying mandates for participating departments or agencies, ensuring effective enforcement and regular review of relevant measures, and integrating such measures into relevant existing arrangements at the national, regional and international level;*
> >
> > *(iii) National governments, supported by other relevant organisations as appropriate, using tools such as: accreditation, certification, audit or*

[20] United Nations, Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Geneva, 1 - 5 December 2008, *Report of Meeting of States Parties*, BWC/MSP/2008/5, 12 December 2008. Available at http://unog.ch/bwc and at http://www.opbw.org

licensing for facilities, organizations or individuals; requirements for staff members to have appropriate training in biosafety and biosecurity; mechanisms to check qualifications, expertise and training of individuals; national criteria for relevant activities; and national lists of relevant agents, equipment and other resources.

(iv) Ensuring measures adopted are practical, sustainable, enforceable, are readily understood and are developed in concert with national stakeholders[21]*, avoid unduly restricting the pursuit of the biological sciences for peaceful purposes, are adapted for local needs, and appropriate for the agents being handled and the work being undertaken, including through applying appropriate risk assessment and risk management strategies.*

(v) Building networks between scientific communities and academic institutions and increasing interaction with professional associations and working groups at the national regional and international level, including through dedicated workshops, seminars, meetings and other events, as well as using modern information technologies and appropriate risk communication strategies and tools;

(vi) International cooperation on biosafety and biosecurity at the bilateral, regional and international levels, in particular to overcome difficulties encountered by some States Parties where additional resources, improved infrastructure, additional technical expertise, appropriate equipment and increased financial resources are needed to build capacity.

(vii) The Implementation Support Unit, in accordance with its mandate, facilitating networking activities, maintaining lists of relevant contacts, and acting as a clearing house for opportunities for international cooperation and assistance on biosafety and biosecurity, including through tools such as a database containing information on such opportunities for international cooperation and assistance.

40. The Meeting of States Parties in 2008 also addressed awareness raising and education and noted in their report[22] that:

25. Having considered the oversight of science, States Parties recognised the value of developing national frameworks to prohibit and prevent the possibility of biological agents or toxins being used as weapons, including measures to oversee relevant people, materials, knowledge and information, in the private and public sectors and throughout the scientific life cycle. Recognising the need to ensure that such measures are proportional to risk, do not cause unnecessary burdens, are practical and usable

[21] *In this report, the term "stakeholders" refers, as appropriate according to national circumstances, to relevant actors such as scientists, researchers and other professionals in the life sciences; editors and publishers of life science publications and websites; and organizations, institutions, government agencies, and private companies acting in life sciences research or education, and any other legal entity that is involved in the stockpiling, transport or use of biological agents, toxins or other resources relevant to the Convention.*

[22] United Nations, Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Geneva, 1 - 5 December 2008, *Report of Meeting of States Parties*, BWC/MSP/2008/5, 12 December 2008. Available at http://unog.ch/bwc and at http://www.opbw.org

and do not unduly restrict permitted biological activities, States Parties agreed on the importance of involving national stakeholders in all stages of the design and implementation of oversight frameworks. States Parties also noted the value of harmonizing, where possible and appropriate, national, regional and international oversight efforts.

26. States Parties recognized the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including for bioterrorism. States Parties noted that formal requirements for seminars, modules or courses, including possible mandatory components, in relevant scientific and engineering training programmes and continuing professional education could assist in raising awareness and in implementing the Convention.

27. States Parties agreed on the value of education and awareness programmes:

> *(i) Explaining the risks associated with the potential misuse of the biological sciences and biotechnology;*
>
> *(ii) Covering the moral and ethical obligations incumbent on those using the biological sciences;*
>
> *(iii) Providing guidance on the types of activities which could be contrary to the aims of the Convention and relevant national laws and regulations and international law;*
>
> *(iv) Being supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications, and audio-visual materials;*
>
> *(v) Addressing leading scientists and those with responsibility for oversight of research or for evaluation of projects or publications at a senior level, as well as future generations of scientists, with the aim of building a culture of responsibility;*
>
> *(vi) Being integrated into existing efforts at the international, regional and national levels.*

28. Having considered codes of conduct, States Parties agreed that such codes can complement national legislative, regulatory and oversight frameworks and help guide science so that it is not misused for prohibited purposes. States Parties recognised the need to further develop strategies to encourage national stakeholders to voluntarily develop, adopt and promulgate codes of conduct in line with the common understandings reached by the 2005 Meeting of States Parties and taking into account discussions at the 2008 Meeting of Experts.

29. States Parties noted the importance of balancing "top-down" government or institutional controls with "bottom-up" oversight by scientific establishments and

scientists themselves. Within the framework of oversight, States Parties recognised the value of being informed about advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention and the necessity of strengthening ties with the scientific community. States Parties welcomed the important contributions made to their work by the scientific community and academia, including national and international academies of science and professional associations, as well as industry-led initiatives to address recent developments in science and technology, and encouraged greater cooperation between scientific bodies in various States Parties.

41. It is especially to be noted that paragraph 26 stated:

> *States Parties noted that **formal requirements** for seminars, modules or courses, including possible **mandatory components**, in relevant scientific and engineering training programmes and continuing professional education could **assist in raising awareness and in implementing the Convention.*** [Emphasis added].

42. The outcome from the consideration of biosafety and biosecurity – and thus of biorisk management, and of education and awareness raising as it emerged during the inter-sessional programme was carried forward at the Seventh Review Conference in December 2011 in the language agreed in the *Final Declaration* for Article IV on National Implementation which stated:

> *13. The Conference notes the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to:*
>
> *(a) implement voluntary management standards on biosafety and biosecurity;*
>
> *(b) encourage the consideration of development of appropriate arrangements to promote awareness among relevant professionals in the private and public sectors and throughout relevant scientific and administrative activities and;*
>
> *(c) promote amongst those working in the biological sciences awareness of the obligations of States Parties under the Convention, as well as relevant national legislation and guidelines;*
>
> *(d) promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins;*
>
> *(e) encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct;*
>
> *(f) strengthen methods and capacities for surveillance and detection of outbreaks of disease at the national, regional and international levels, noting that the International Health Regulations (2005) are important for building capacity to prevent, protect against, control and respond to the international spread of disease;*

> *(g) prevent anyone from developing, producing, stockpiling, or otherwise acquiring or retaining, transporting or transferring and using under any circumstances, biological agents and toxins, equipment, or their means of delivery for non-peaceful purposes.*

Effective Biosafety and Biosecurity for the BTWC

43. An overview of what might usefully be achieved in regard to the implementation of Article IV of the Convention is set out in the chapter[23] on *Article IV: National Implementation: Education, Outreach and Codes of Conduct* of the Bradford *Key Points for the Seventh Review Conference.* This chapter outlined on page 130 the work that had been undertaken to harmonise biosafety (biorisk management) and dual-use biosecurity awareness raising, education and training by noting the work that had been carried out by Canada:

> *54. In order to promote safety and security with the respect to human pathogens and toxins Canada enacted national domestic legislation known as the Human Pathogens and Toxins Act in 2009[24]. This states that The Purpose of the Act is to "establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins." Although the training requirements specified in the Act have yet to be developed, the Act includes a stipulation that Biosafety Officers require Qualifications. It is understood that …in 2012, the Canadian Biosafety Standards and Guidelines (CBSG) will specify the requirement (The Standard) for trained staff and guidance (The Guidelines) as to what this actually means will be set out. The CBSG will replace Canada's current Laboratory Biosafety Guidelines[25] and will become the new biosafety standard in Canada. Until this time the requirement for trained staff is currently included in the Laboratory Biosafety Guidelines for Canada.*

44. Although core competence and training requirements are included in the CEN *Biosafety Professional Competence Agreement* (addressed above), no consensus presently exists on what the curricular content should be for sustainable biorisk management and/or education and awareness raising programmes. The Canadian example, however, usefully illustrates how one State Party to the BWC seeks to strengthen the Convention through the development of training provision for biosafety professionals thus[26]:

> *… in recognition of requirements for qualifications and training, in order to meet the biosafety and biosecurity challenges of the 21st century, Canada's Public Health Agency (PHAC) is involved in the development and dissemination of hybrid applied biosafety and dual-use biosecurity training material that addresses both the biosafety*

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[23] Simon Whitby, Cathy Bollaert and Malcolm R. Dando, *Article IV: National Implementation: Education, Outreach and Codes of Conduct* on pages 113 – 139 of University of Bradford, *Key Points for the Seventh Review Conference,* September 2011. Available at http://www.brad.ac.uk/acad/sbtwc and in the Think Zone for the Seventh Review Conference at unog.ch/bwc.

[24] The Human Pathogens and Toxin Act. Canada. Available at: http://lois-laws.justice.gc.ca/eng/acts/H-5.67/page-1.html

[25] Laboratory Biosafety Guidelines (3rd ed.). 2004. Public Health Agency, Canada. Available at: http://www.phac-aspc.gc.ca/lab-bio/res/blk-acb/lbg-ldmbl-eng.php

[26] Simon Whitby, Cathy Bollaert and Malcolm R. Dando, *Article IV: National Implementation: Education, Outreach and Codes of Conduct* on pages 113 – 139 of University of Bradford, *Key Points for the Seventh Review Conference,* September 2011. Available at http://www.brad.ac.uk/acad/sbtwc and in the Think Zone for the Seventh Review Conference at unog.ch/bwc.

and biorisk management, as well as dual-use biosecurity concerns that necessarily address a range of issues both within the laboratory and beyond the laboratory door. In this regard ***national implementation legislation*** *is regarded as a foundation upon which the development of national training provision should be built. Importantly, the Canadian awareness-raising, education and training initiative can be regarded as a model of best practice for the training of biosafety professionals in the area of biosecurity since it acknowledges that professionals require an understanding of dual-use biosecurity issues of concern as well as thorough grounding in biosafety and biorisk management.*

45. In a joint initiative between Canada's Public Health Agency (PHAC), the Carleton University, Ottawa, and the University of Bradford, a 10-Day intensive workshop[27] on applied dual-use biosecurity, biosafety and bioethics is being held on 13 – 24 August 2012. The course is entitled *The Advanced Certificate in International Biological Sciences Security Management* and has the following objectives:

This 10 – day, intensive program has a focus on Canadian and international biosafety, dual-use biosecurity and bioethics and is intended for the training of personnel in facilities handling human pathogens and toxins, bringing issues of dual-use to a broader community, and to enhance biosafety and biosecurity practices in a Biological Sciences Security Management framework nationally and internationally. This cooperative program… is the first step in the development of a joint curriculum on biosafety and biosecurity for life scientists in Canadian institutions.

What you will learn:

1. *The concepts of biosafety and biosecurity and its relevance to biosecurity within the laboratory.*
2. *Management of biosafety and biosecurity risks.*
3. *Dual-use conundrums and dilemmas that arise due to the impact of science and technology on society.*
4. *Ethical, legal and social relevance of dual-use biosecurity.*
5. *Approaches to the responsible conduct of research and other work.*
6. *Facilitate further research into 'dual-use' biosecurity issues and develop policies and practices that will enhance responsible conduct of research and other work to prevent the misuse of knowledge generated by life and associated sciences.*

Learning Outcomes

After successfully completing this ten-day workshop, participants will be able to:

- *Explain the international and national controls with regards to biosafety, biosecurity and bioethics applicable to facilities and associated scientists handling pathogens.*
- *Apply a framework for risk assessment to biosafety, biosecurity and dual-use risks and hazards associated with pathogens.*

[27] See information at http://www1.carleton.ca/.../Program-Notification-NPSIA-PTD-PHAC-Adv-Cert-International-Bio-Sci-Security-August-2012-eng-a.pdf

- *Analyse the ethical and social responsibilities of life scientists with reference to the responsible conduct of research and other work*
- *Integrate dual-use biosecurity, biosafety and bioethical issues and concerns into their program.*
- *Contribute to the development and implementation of relevant country-specific and institutional mechanisms, guidelines, regulations and legislation.*
- *Explain the key components of administrative controls that a facility has to put in place to mitigate biosafety and biosecurity risks.*
- *Develop a strategy for the implementation of a biosafety management program in a facility handling pathogens*
- Organise and synthesise ideas and questions on dual-use biosecurity, biosafety and bioethics relevant to the conduct of research and other work with pathogens.

Overall Appreciation

46. The Meetings of Experts and of the States Parties in 2012 will, under the Standing Agenda item on *Review of developments in the field of science and technology related to the Convention* address:

> *(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;*

47. This Briefing Paper in considering this topic has focused on how to strengthen the Convention through achieving full and effective biosecurity in the life sciences. The paper has examined the role of biorisk management measures by examining the requirements set out in the WHO's Biorisk Management *Laboratory Biosecurity Guidance*, as well as the requirements for and application of the CEN *Laboratory Biorisk Management Agreement* (CWA: 15793), and the CEN *Biosafety Professional Competence Agreement* (CWA: 16335). Whilst the WHO Biorisk Management *Laboratory Biosecurity Guidance* together with the CEN *Laboratory Biorisk Management Agreement* (CWA: 15793) articulate comprehensive biorisk management-related recommendations, they set out what is to be expected. For effective strengthening of the Convention, the States Parties are urged to adopt universally agreed practices, principles and standards. Whilst the CEN *Biosafety Professional Competence Agreement* (CWA: 16335) specifies core tasks, a model role profile and training requirements for biosafety professionals, implementation of this Agreement although widespread is not universal. As is the case with CEN *Laboratory Biorisk Management Agreement* (CWA: 15793), the CEN *Biosafety Professional Competence Agreement* (CWA: 16335) has not been universally adopted.

48. It is particularly to be noted that the *Laboratory Biorisk Management Agreement* recognises that efficient and effective biological risk management is compatible with a **broad** appreciation of biosecurity concerns including those beyond the laboratory door, as well as biosafety and biosecurity within the laboratory. Indeed the *Laboratory Biorisk Management Agreement* as well as the *Biosafety Professional Competence Agreement* are explicit in their recognition of the importance of ensuring that those engaged in the life sciences are aware of the ethical implications of their work. It is also clear from the above that there is considerable

variation in the curriculum content in respect of education and training programmes aimed at the various stakeholders involved in the implementation of effective biosecurity.

49. The recognition of the importance of the implementation of national measures relating to biosafety and biosecurity, as well as the importance of awareness-raising and education that were agreed by the States Parties at the 2008 Meeting of States Parties was noted above. So too was the importance of the implementation by States Parties of such measures through the language agreed on Article IV in the *Final Declaration* of the 2011 Seventh Review Conference.

50. In regard to national implementation, the Canadian Human Pathogens and Toxins Act is particularly noteworthy in that it establishes a legally-binding obligation for the qualification of biosafety officers. The existence of this requirement will be important in demonstrating Canadian compliance with both the WHO International Health Regulations (IHR) as well as United Nations Security Council Resolution (UNSCR) 1540 both of which place strong obligations upon member states to create such provisions[28].

51. It is welcome that in developing a biorisk management – dual-use bioethics training initiative in collaboration with the University of Bradford and the Carleton University, the Canadian Public Health Agency recognises that efficient and effective biological risk management requires that all three concerns – biosafety, biosecurity and ethics – are addressed both within and beyond the laboratory doors.

52. Although there may be a case also for the creation of focused awareness-raising, education and training initiatives, for example, in regard to the need for the development of curricula that address practical/technical aspects (biosafety, biosecurity and risk assessment) and conceptual (principles, norms, ethical) issues separately, it is evident that joint training initiatives such as that being developed by both Canada and Bradford will be more sustainable if they meet the following criteria:

a. that a wide audience is reached, and

b. that information is presented that is of relevance to **both** national and international contexts.

There is encouragement that both of these criteria can be achieved through online distance learning platforms - an approach already being adopted to good effect by the University of Bradford who have just completed online distance learning dual-use biosecurity training to approximately 60 practicing life- and associated scientists in a wide range of countries around the world[29].

[28] Lela Bakanidze, Paata Imnadze, and Dana Perkins, Biosafety and biosecurity as essential pillars of international health security and cross-cutting elements of biological nonproliferation, *Biomed Central*, BMC Public Health. 2010; 10(Suppl 1): S12. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3005572/

[29] See the University of Bradford's Applied Dual-Use Biosecurity Education: Online Distance Learning Module 30 Masters Level Credits, Available at: http://www.brad.ac.uk/bioethics/TraintheTrainer/30CreditBiosecurityModule/. Approximately 60 participants have completed and have graduated from this course that has been finance by the Biosecurity Engagement Program, United States Department of State. Participants have completed the course via online distance learning. The participants have been located in the following countries: Argentina, Brazil, Jordan, Kenya, Iraq, Indonessia, Malaysia, Mali, Pakistan, Qatar, Russia, South Africa, Nigeria, Ukraine.

53. The Canadian example is particularly noteworthy in that it provides a compelling practical example of how the implementation of 'top-down' national implementation measures can enhance biological risk management by ensuring that all three elements – biosafety, biosecurity and ethics – are addressed both within and beyond the laboratory doors through a fruitful State Party collaboration with academia by building sustainable training capabilities in this area.

Conclusions

54. It is recommended that the States Parties in considering the Standing Agenda item on advances on science and technology when considering:

> *(c) possible measures for strengthening national biological risk management, as appropriate, in research and development involving new science and technology developments of relevance to the Convention;*

should recognise the following points:

a. The steps taken by the World Health Organisation (WHO) to enhance both biosafety through the *Biosafety Manual* issued in 2004 and biosecurity through the *Laboratory Biosecurity Guidance* issued in September 2006 are valuable steps towards strengthened biological risk management.

b. It is more accurate and comprehensive to use the term *activities* as in consideration of misuse/dual-use the focus needs to be on *activities* in the life sciences – whatever their nature and regardless of whether they be described as research, exploratory development or development.

c. Although laboratory biosafety and biosecurity are essential, it is important to recognise the broader application of biosafety and biosecurity beyond the laboratory doors.

d. Standards such as the CEN *Laboratory Biorisk Management Agreement* (CWA 15793) and the CEN *Biosafety Professional Competence Agreement* (CWA 16335) are welcome steps towards internationally agreed standards and States Parties should be encouraged to adopt these standards nationally.

e. The joint initiative being undertaken between Canada's Public Health Agency (PHAC), the Carleton University, Ottawa, and the University of Bradford to launch a course leading to *The Advanced Certificate in International Biological Sciences Security Management* should be welcomed and States Parties should be encouraged to launch similar courses leading to internationally recognised qualifications in biosafety, biosecurity and ethics for those engaged in the life sciences.

f. The States Parties should recognise that full and effective biological risk management – through biosafety, biosecurity and ethics – is a key requirement for the effective national implementation of the Convention in accordance with Article IV.