GUIDE

to Implementing the Biological Weapons Convention







United Nations

This Guide was prepared by the United Nations Office for Disarmament Affairs (UNODA), as part of a project funded under European Union Council Decision CFSP 2019/97 in support of the Biological Weapons Convention (BWC) in the framework of the European Union Strategy against Proliferation of Weapons of Mass Destruction.

For more information, please contact the BWC Implementation Support Unit, United Nations Office for Disarmament Affairs at bwc@un.org.

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The Guide includes guidance and suggestions on how to implement the BWC at the national level. Nothing in this Guide is intended to imply or confer any additional obligations on States Parties. The Guide is intended as a practical aid for persons working on the implementation of the BWC at the national level. The Guide has no formal status, please refer to the BWC for the legally binding obligations deriving from it.

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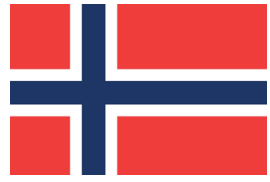

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FOREWORD

Biological weapons can be used not only to attack humans, but also livestock and crops. In addition to causing serious illness and death, the use of such weapons could result in widespread disruption and immense economic harm. Diseases caused by biological weapons would not confine themselves to national borders and could spread rapidly around the world.

Adopted with the objective to exclude completely the possibility of biological agents and toxins being used as weapons, the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, commonly known as the Biological Weapons Convention (BWC) or Biological and Toxin Weapons Convention (BTWC), effectively bans the development, production, stockpiling, acquisition, retention and use of biological and toxin weapons.

Despite this prohibition, many challenges face the global community regarding such weapons, including those resulting from the potential misuse of advances in science and technology and the eroding technological barriers to acquiring and using them. In view of these challenges, the full and effective national implementation of the Convention is of the utmost importance.

The *Guide to Implementing the Biological Weapons Convention* has been developed by the United Nations Office for Disarmament Affairs, (UNODA), with the support of the European Union and Norway and the contributions of a wide range of BWC experts, to assist States Parties in their efforts to implement the Convention at the national level. Its aim is to provide practical guidance to BWC national contact points and other responsible officials on the implementation of the BWC in the national legal and institutional frameworks in fulfilment of their State's obligations under the Convention. This *Guide* does not, however, pretend to be exhaustive or to comprehensively reflect all possible implementing measures. It is intended only as a practical aid and has no formal status; the suggestions included herein as well as the descriptions of the BWC do not necessarily reflect the views of the States Parties to the BWC. In no case is this *Guide* intended to imply or confer any additional obligations on States Parties to the Convention.

The *Guide* is available in all official languages of the UN.

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The *Guide* was prepared as part of a project funded under European Union (EU) Council Decision CFSP 2019/97 in support of the BWC in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction. It builds on pre-existing work conducted by UNODA in the framework of previous EU instruments in support of the BWC, to which a wide range of recognised experts from BWC States Parties, the 1540 Committee's Group of Experts and non-governmental organisations, as well as independent experts contributed.

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ABBREVIATIONS

1925 Geneva Protocol	Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare
BW	Biological weapons
BWC	Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, commonly known as the Biological Weapons Convention
CARICOM	Caribbean Community
CBM	Confidence-Building Measure
CBRN	Chemical, Biological, Radiological and Nuclear
CWC	Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, commonly known as the Chemical Weapons Convention
EU	European Union
EU-CBRN CoE	European Union - Chemical, Biological, Radiological and Nuclear Risk Mitigation Centres of Excellence
FAO	Food and Agriculture Organization of the United Nations
GHSA	Global Health Security Agenda
GMO	Genetically Modified Organism
ICRC	International Committee of the Red Cross
IFRC	International Federation of Red Cross and Red Crescent Societies
IHR	International Health Regulations (2005)
INTERPOL	International Criminal Police Organization
IPPC	International Plant Protection Convention

IPU	Inter-Parliamentary Union
ISU	Implementation Support Unit
JEE	Joint External Evaluation
NAP	National Action Plan
NAPHS	National Action Plan for Health Security
NIM	National Implementation Measures
OECD	Organisation for Economic Co-operation and Development
OPCW	Organisation for the Prohibition of Chemical Weapons
PGA	Parliamentarians for Global Action
Resolution 1540	United Nations Security Council resolution 1540 (2004)
SDG	Sustainable Development Goal
UN	United Nations
UNODA	United Nations Office for Disarmament Affairs
UNODC	United Nations Office on Drugs and Crime
VERTIC	Verification Research, Training and Information Centre
WCO	World Customs Organization
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WOAH	World Organisation for Animal Health, founded as OIE

INTRODUCTION

Who is this *Guide* for?

The full and effective implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, more commonly known as the Biological Weapon Convention (BWC) or Biological and Toxin Weapons Convention (BTWC), requires actions to be taken by all States Parties at the national level. BWC Review Conferences have called upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures to enhance domestic implementation of the Convention.

This *Guide* is primarily intended to provide an overview of the national implementation process and obligations stemming from the BWC. Its primary audience is States Parties initiating or already engaged in the BWC implementation process or States Parties interested in assessing their implementing framework. The *Guide* outlines the types of legislative, regulatory and other measures that States Parties may consider developing and adopting in order to effectively implement the BWC. It also outlines possible synergies and overlaps with other instruments such as United Nations Security Council resolution 1540 (2004) and the International Health Regulations (2005), to assist States Parties in streamlining their implementation efforts.

The range of implementing measures is wide, and these measures may take numerous forms and functions at various levels (legislation, regulations, codes of conduct, good practices, etc.). The determination of the relevant set of implementing measures for each State Party may vary depending on a number of factors (size of the country, its geography, the state of development of its bioindustry or trade, its legal system and existing legal and institutional frameworks, its participation in regional economic cooperation or integration organisations, etc.). There is no one solution that fits all. Rather, it is up to each State Party, based on its own assessment of the biological risks it faces and in consideration of all relevant factors, to determine what measures may best enable it to ensure compliance with the Convention.

This *Guide* does not pretend to be exhaustive and does not review the entire range of possible measures that may contribute to the implementation of the Convention. Instead, it focuses on the legislative, regulatory and other implementing measures which States Parties may adopt in furtherance of, primarily, Article IV of the Convention. Other measures than those referenced in this *Guide* may, therefore, also be necessary.

The *Guide* is divided into Modules to facilitate its use. Readers do not need to read the *Guide* in full but can easily access the information they need:

Module I	outlines the various steps in the implementation process
Module II	present possible approaches for the establishment of the legislative and regulatory frameworks, and the institutional framework for the implementation of the Convention
Modules III to VII	each deal with a specific thematic area to be considered in implementing the Convention: penal aspects; transfer control regimes; biosafety and biosecurity; bioemergency preparedness and response; and promotion of international cooperation, assistance and exchanges in biological sciences and technology.

The *Guide* also has five annexes.

- Annex 1 provides a glossary of terms.
- Annex 2 provides an indicative list of the implementing measures States Parties may consider taking.
- Annex 3 points to resources and assistance tools which States Parties engaged in the implementation process could find useful.
- Annex 4 provides information on available assistance programmes and initiatives related to BWC implementation.
- Annex 5 lists reference materials used in the development of this *Guide*.

Throughout the *Guide*, readers will also find colored boxes:

- Specific aspects of relevance to BWC implementation are highlighted in blue boxes.
- Examples of national implementation experiences are provided in orange boxes.
- States Parties seeking assistance for BWC implementation will find specific resources, tools, programmes and initiatives of relevance to each thematic area addressed in purple boxes.

The BWC in a nutshell

Adopted as a result of prolonged efforts by the international community to establish a new instrument that would supplement the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, commonly known as the 1925 Geneva Protocol, the BWC was the first multilateral disarmament treaty to ban an entire category of weapons.

The BWC effectively prohibits the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons, and is a key element in the international community's efforts to address the proliferation of weapons of mass destruction. It was opened for signature on 10 April 1972 and entered into force on 26 March 1975. Since then, many States have joined the Convention, which currently has 184 States Parties and four Signatory States. There are nine States which have neither signed nor acceded to the Convention.

Box 1 – Joining the BWC

Information on joining the BWC can be found in *The Biological Weapons Convention – An Introduction* at https://www.un.org/disarmament/publications/the-biological-weapons-convention/, as well as on the UNODA website at https://www.un.org/disarmament/biological-weapons/about/universalization-and-joining-the-bwc/

Information on the status of the BWC can be found at https://www.un.org/disarmament/biological-weapons/about/membership-and-regional-groups.

The BWC is relatively short, comprising only 15 articles. The text of the BWC is available at https://treaties.unoda.org/t/bwc.

Over the years, at five-yearly Review Conferences, held to review the operation of the BWC and ensure that it remains relevant and effective in light of changes in science and technology, politics and security, States Parties have also reached a number of additional understandings related to the Convention. The final declarations adopted at the Review Conferences are available at UNODA Meetings Place (https://meetings.unoda.org).

Table 1 – BWC key provisions

ARTICLE I	Undertaking never under any circumstances to develop, produce, stockpile, acquire or retain biological weapons.
ARTICLE II	Undertaking to destroy biological weapons or divert them to peaceful purposes.
ARTICLE III	Undertaking not to transfer, or in any way assist, encourage or induce anyone to manufacture or otherwise acquire biological weapons.
ARTICLE IV	Requirement to take any national measures necessary to prohibit and prevent the development, production, stockpiling, acquisition or retention of biological weapons within a State's territory, under its jurisdiction, or under its control.
ARTICLE V	Undertaking to consult bilaterally and multilaterally and cooperate in solving any problems which may arise in relation to the objective, or in the application, of the BWC.
ARTICLE VI	Right to request the United Nations Security Council to investigate alleged breaches of the BWC, and undertaking to cooperate in carrying out any investigation initiated by the Security Council.
ARTICLE VII	Undertaking to assist any State Party exposed to danger as a result of a violation of the BWC.
ARTICLE X	Undertaking to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and information for peaceful purposes.

STATUS OF UNIVERSALIZATION OF THE BWC

(April 2023)

185 States Parties

4 Signatory States

8 Non-Signatory States

Map No. 4634 Rev. 1 April 2023

UNITED NATIONS Geospatial

The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

Dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the Parties. Final boundary between the Republic of Sudan and the Republic of South Sudan has not yet been determined.

MODULE 1 – LAYING THE GROUNDWORK

BWC national implementation is a process to domestically implement the Convention within the specific legal system of a State Party and give effect to the obligations embodied in the BWC. Given the variety of legal systems around the world, the implementation of specific obligations is left to the discretion of States Parties. The aim of this Module is to guide States Parties through the initial steps in the BWC implementation process. It discusses the need for coordinating the national implementation process amongst relevant stakeholders. It also provides general guidance on the conduct of a self-assessment of a State Party's existing legal and institutional framework and an analysis of the identified gaps. This Module also provides guidance on the elaboration of a national action plan for BWC national implementation.

1.1 Overview of the national implementation obligation

In accordance with the general principles of international law, in becoming a State Party to the BWC, a State consents to be bound by its provisions and to perform its obligations in good faith. To ensure that States Parties fulfil their international obligations under the BWC, the adoption of national implementing measures is essential. This is the case regardless of whether the State Party's legal system is dualist, i.e. international and national law are treated as separate systems, operating at different levels and requiring a specific domestic legal act to give effect to a treaty; or monist, i.e. international and national law are treated as one system, and mere ratification of, or accession to, a treaty automatically leads to its incorporation into the domestic legal order. Because the BWC lacks specific provisions to make it automatically applicable,[1] the adoption of implementing measures is required in all States Parties.

The obligation to take national measures is also clearly established in Article IV of the Convention. When the BWC was negotiated in the late 1960s and early 1970s, Article IV was a complete innovation. The requirement to enact domestic legislation had no direct precedent in earlier arms limitation treaties.

1 For example, the BWC does not prescribe penal penalties in case of violation of the prohibitions specified in its Article I. It also does not prescribe the details of the control measures to be taken to prevent prohibited transfers, and does not assign authority for the conduct of such controls.

Box 2 – Article IV of the Convention

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

In addition to the express requirement set forth in Article IV, the implementation of other obligations under the BWC can be facilitated by the adoption of appropriate national measures. For example, several Review Conferences have called for appropriate measures to implement Article III,[2] as well as recognised the need to effectively implement national measures to further implementation of Article X.[3]

National implementing measures are also critical to enable the relevant national authorities to, for example:

- Investigate, prosecute and punish the acts prohibited under the Convention;
- Prevent access to, and diversion of agents and toxins, for use for harmful purposes; and
- Monitor and take action in the event of suspicious transfers of dangerous biological agents and toxins, or related equipment and technologies.

National implementing measures may also be needed to, for example, enable the relevant national authorities to collect the data necessary for the annual submissions of the Confidence-Building Measures (CBMs) to the BWC Implementation Support Unit.

2 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article III, paragraph 9; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article III, paragraph 9; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article III, paragraph 8; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 2; and BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 1.

3 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article X, paragraph 70; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article X, paragraph 60; and BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article X, paragraph 52.

Box 3 – Confidence-Building Measures (CBM)

At the Second Review Conference in 1986, States Parties agreed that they should annually submit Confidence-Building Measures (CBMs) to prevent or reduce the occurrence of ambiguities, doubts and suspicions and to improve international cooperation. The precise modalities for the information exchange were agreed by an expert meeting in 1987. Subsequent Review Conferences have urged and called upon all States Parties to annually submit CBMs, as have relevant annual resolutions adopted by the United Nations General Assembly.

The CBMs provide an opportunity for States Parties to demonstrate commitment to fulfilling their BWC obligations by providing relevant data. They have to be returned no later than 15 April each year and are based on agreed forms providing information on: research centres and laboratories meeting very high national or international safety standards; biodefence research and development programmes; infectious disease outbreaks, and similar occurrences caused by toxins, that may be of interest in the BWC context; publication policies related to scientific activities relevant to the BWC; national legislative and other measures to implement BWC obligations; past offensive and defensive biological research and development activities; and vaccine production facilities.

Further information on CBMs can be found in the Guide to Participating in the Confidence-Building Measures of the Biological Weapons Convention at https://www.un.org/disarmament/publications/more/cbm-guide/, as well as on the UNODA website at https://www.un.org/disarmament/biological-weapons/confidence-building-measures/. The eCBM facility, which serves as the repository for all the CBMs submitted and enables the online generation and submission of the annual CBM reports, is accessible at https://bwc-ecbm.unog.ch/.

Adopting national measures for BWC implementation may also contribute to States Parties' efforts towards the implementation of other international instruments such as United Nations Security Council resolution 1540 (2004)[4], the International Health Regulations (2005), or resolutions of the World Health Assembly, and the fulfilment of other international or regional obligations.

4 An overview of relevant measures to implement UN Security Council resolution 1540 (2004) can be found in the 1540 Matrix Template, as approved by the 1540 Committee and accessible from the 1540 Committee website at https://www.un.org/en/sc/1540/national-implementation/1540-matrices.shtml

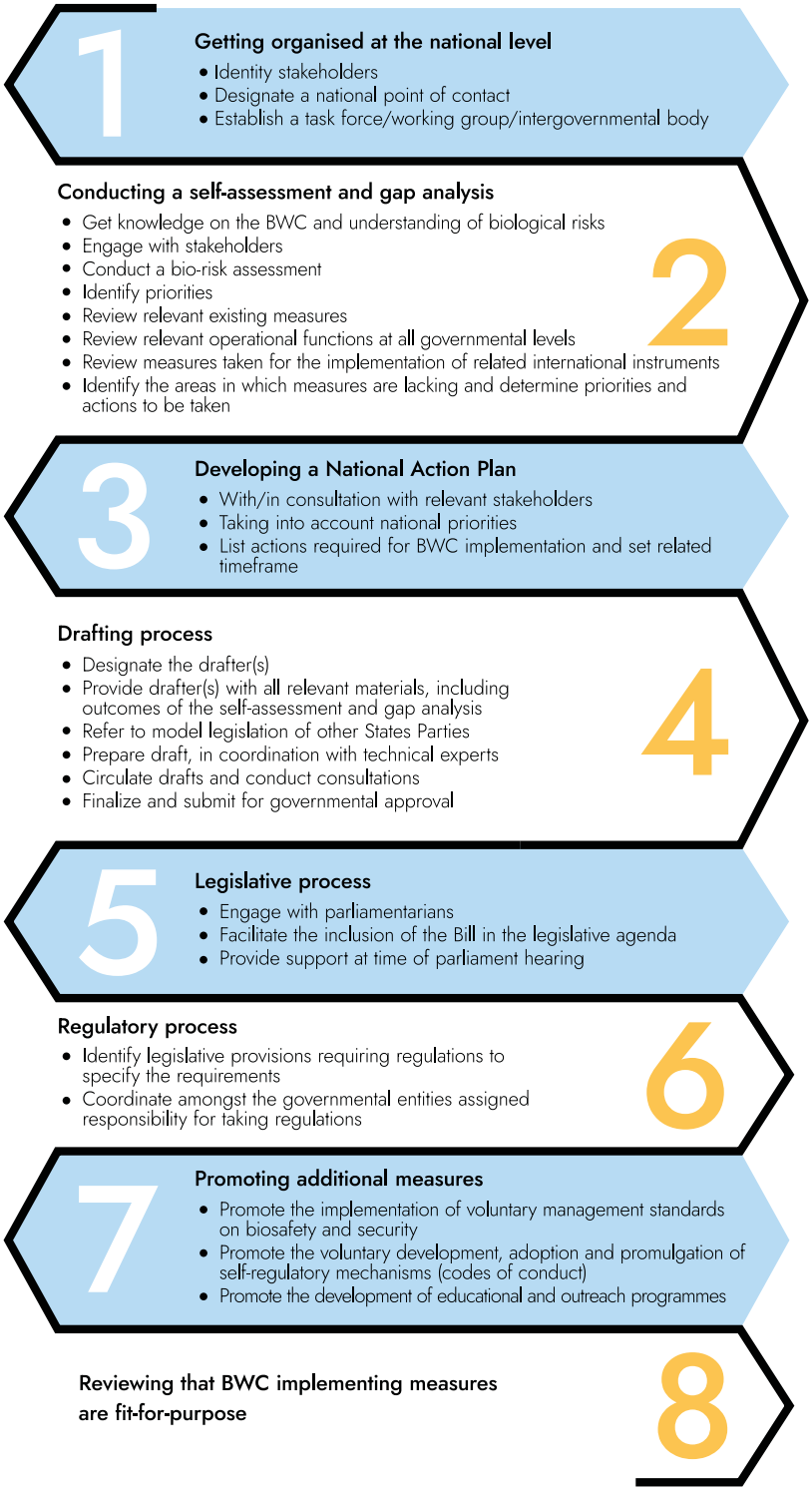
▲ The Conference of the Committee on Disarmament holds negotiations in the Council Chamber at the Palais des Nations, Geneva, in 1969.
Photo credit: UNOG.

In addition, the full and effective implementation of the BWC contributes to advancing progress towards the achievement of the Sustainable Development Goals (SDGs). In particular with regard to SDG 3 on good health and well-being, full and effective implementation of the BWC can strengthen the capacity of all countries for early warning, risk reduction and management of national and global health risks. It also contributes to the achievement of SDG 16 on peace, justice and strong institutions, by reducing all forms of violence and related death rates everywhere and strengthening the institutional capacities of States to prevent violence, terrorism and crime.

There is no agreed checklist of the necessary measures to be taken by States Parties for BWC implementation. The exact scope and type of such measures may in fact vary depending on several factors, including the specific circumstances and legal systems of each State Party. Guidance and suggestions on certain measures, which States Parties should consider taking to implement their obligations under the BWC, can be found in the final documents of the Review Conferences as well as the reports of the Meetings of States Parties.

An indicative list of BWC implementing measures is provided in Annex 2. In no case is this indicative list intended to alter in any manner the obligations of States Parties as established under the Convention.

Figure 1 – The BWC implementation process



1.2 Getting organised at the national level

1.2.1 Identifying relevant stakeholders

The BWC relates to many sectors. Certain ministries, government departments and agencies have specific functions and expertise that are essential to the national implementation of a State Party's obligations under the BWC. Other stakeholders, such as industries, research centres, laboratories and universities, also have an important role to play in implementing the Convention.

Therefore, it is critical to ensure the early involvement of, and to engage through consultations with, all relevant stakeholders in the preparation and in the elaboration of the implementing measures, also giving due consideration to the equal participation of women and men. Such engagement will allow to:

- Consider the perspectives of all stakeholders, as they may have various and sometimes contradictory interests;
- Ensure the relevance of the implementing measures by taking into account existing legal and institutional frameworks, and specific operational factors;
- Avoid the duplication of measures serving the same purposes, and ensure harmonisation and coordination with existing measures, including existing control regimes and requirements applying to relevant facilities and activities;
- Address misconceptions, such as on the purpose and expected outcome of the implementation process;
- Facilitate the future enforcement of the BWC implementing measures by fostering a shared sense of ownership and responsibility between relevant stakeholders.

To identify relevant stakeholders, States Parties should review each article of the BWC and link roles and responsibilities of their respective national authorities with specific obligations. The list below is not exhaustive, but BWC implementation may require the involvement of, and cooperation with, for example:

- The Office of the Prime Minister or Head of Government;
- The Office of the Attorney-General;
- Ministries of Agriculture, the Environment, Foreign Affairs, Defence, Health, Education, Science and Technology, Industry, Interior, Justice, Trade, Transportation, International Development and Co-operation;

- Parliamentarians;
- Border control authorities, including customs and port authorities;
- Enforcement authorities;
- Emergency management authorities;
- Plant health inspectorate, and veterinary inspectorate;
- Chambers of commerce;
- Academies of science;
- Research centres/institutes, and laboratories;
- Relevant corporate/industrial entities;
- Biotechnology industry and related associations; and
- Professional bodies such as biosafety associations.

1.2.2 Designating a national point of contact

The Sixth and subsequent Review Conferences encouraged States Parties to designate a national point of contact for coordinating national implementation of the BWC and communicating with other States Parties and relevant international organisations.

As further discussed below, the Review Conferences have not specified a single approach or institutional structure for the point of contact, and the responsibilities and powers assigned to points of contact are therefore not the same in all States Parties. In some States Parties, the point of contact only serves as a liaison between the BWC Implementation Support Unit and other States Parties, while the responsibility for the implementation process is assigned to others. In other States Parties though, the national point of contact may play a critical role in the implementation process, in particular at the initial stage by:

- Securing the political will and commitment to engage the State Party in the implementation process, and related allocation of resources to the conduct of this process;
- Coordinating international cooperation and, where needed, seeking assistance from other States Parties;
- Identifying stakeholders; and
- Coordinating initial stakeholder consultations.

1.2.3 Establishing a task force, working group or inter-governmental body

States Parties may consider establishing a task force or working group specifically dedicated to the BWC implementation process, composed of relevant stakeholders. Alternatively, they may also consider establishing an inter-governmental body as a more permanent structure, which could also serve as national point of contact, in order to ensure continuous cooperation of all involved in the implementation of the BWC. Alternatively, States Parties could rely on a pre-existing structure established for the implementation of related international instruments such as UN Security Council resolution 1540 (2004), the Chemical Weapons Convention or terrorism conventions.

In all cases, such an entity could be charged with:

- Conducting a self-assessment and gap analysis, and identifying the necessary measures to implement the BWC;
- Elaborating a national action plan for BWC implementation, including by setting priorities;
- Facilitating the preparation of draft texts, and overseeing the drafting process;
- Discussing draft texts, and engaging with non-governmental stakeholders through consultations on the drafts;
- Liaising with relevant ministries and parliamentarians, and facilitating the inclusion of draft texts in the governmental or legislative agenda; and
- Providing clarifications and responding to questions during the governmental or legislative approval process.

Box 4 – Focus on Kenya's experience

Until 2008, the Ministry of Foreign Affairs of Kenya was the national focal point for the BWC. After the 2008 Meeting of States Parties, the need to have the scientific community involved in BWC matters was realized. Consequently, in 2009 Kenya's national focal point on the BWC was changed to the National Council for Science and Technology (NCST), which was a semi-autonomous State Agency (SAGA) under the Ministry of Higher Education, Science and Technology. NCST established the National Biological and Toxin Weapons Committee (NBTWC) in 2009.

The NBTWC was put in place not only to meet Kenya's international obligations as a State Party to the BWC, but also to develop a comprehensive policy and legal framework for national biosecurity.

The terms of reference of the NBTWC were to draft a biosecurity policy and bill, represent Kenya at BWC meetings, prepare country statements and technical presentations for such meetings and coordinate the submission of confidence-building measure (CBM) forms. In 2013,

the National Commission for Science Technology and Innovation (NACOSTI) was established by the Science Technology and Innovation Act 2013 as a successor of the NCST.

Since the inception of the NBTWC, Kenya has been involved in several BWC related activities, including:

- Drafting of the Biosecurity Policy and Biosecurity Bill in 2010. The latter was shared with stakeholders in 2011. The two documents were reviewed in 2020 and shared with the stakeholders;
- Submission of CBM forms since 2010;
- Participation in the local organising committee for the African Regional Workshop on Biosafety and Biosecurity, held in support of UN Security Council resolution 1540 (2004), in Nairobi, in February 2010;
- Participation in BWC meetings (since 2010); and
- Participation in regional workshops on the national implementation of the BWC (since 2010) and regional universalisation workshops (since 2011).

Source: National Commission for Science, Technology and Innovation, National Contact Point/Office of BTWC; and "Implementation of the Biological Weapons Convention in Kenya", by Austin Ochieng Aluoch and Maurice Owuor Ope, in *Improving Implementation of the Biological Weapons Convention, The 2007–2010 Intersessional Process*, jointly published by the United Nations Institute for Disarmament Research and UNODA, 2011.

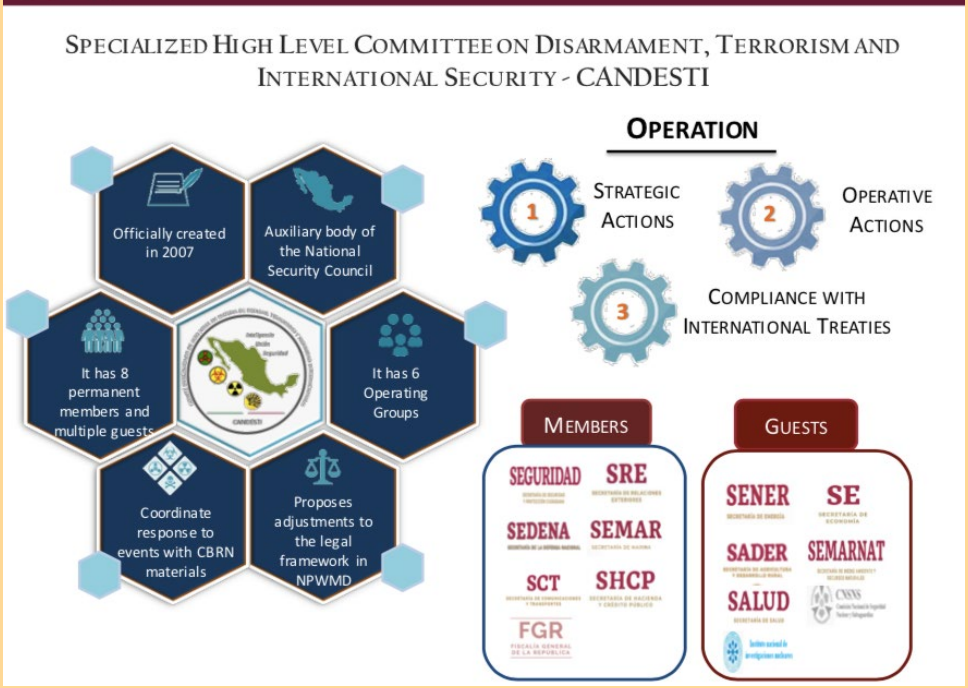
Box 5 – Focus on Mexico's experience

In 2007, Mexico established the Specialized High-Level Committee on Disarmament, Terrorism and International Security (*Comité de Alto Nivel sobre Desarme, Terrorismo y Seguridad Internacional* – CANDESTI) to coordinate the actions of the Executive Power to comply with the international obligations of Mexico in the area of disarmament, terrorism and international security. CANDESTI includes representatives of the Ministries of Foreign Affairs, National Defence, Security and Civil Protection, Communications and Transportation, the Marine, Finance and the General Prosecutor.

Among others, CANDESTI was established to:

- Serve, through its General Secretariat and under the coordination of the Ministry of Foreign Affairs, as liaison between Mexico and the mechanisms or organisations established by relevant international treaties and instruments;
- Coordinate the actions of the agencies and entities of the Federal Public Administration for the fulfilment of the obligations established in the international treaties and instruments to which Mexico is a party in matters of disarmament, terrorism and/or international security;
- Analyse and, where appropriate, propose the adoption of legislative, administrative or any other measures necessary to adapt the Mexican legal framework with the obligations set forth in international treaties and instruments to which Mexico is a party;
- Establish the rules for the exchange of reports, data, or technical cooperation between the relevant agencies, related to the obligations of Mexico towards the international community in matters of disarmament, terrorism and/or international security;
- Request, through its General Secretariat, the information required by the bodies and mechanisms established by virtue of international treaties and instruments, from the natural or legal persons affected by them;
- Coordinate with the competent authorities in matters of foreign trade regarding imports and exports of goods and substances provided for in international treaties and instruments.

CANDESTI



Source: *ACUERDO del Consejo de Seguridad Nacional por el que se establece un Comité Especializado de Alto Nivel para coordinar las acciones del Poder Ejecutivo Federal que dan cumplimiento a las obligaciones internacionales del Estado mexicano en el ámbito nacional en materia de desarme, terrorismo y/o seguridad internacionales*, Official Gazette of Mexico 28/05/2007; and presentation by Mexico at the 2019 Meeting of Experts on Strengthening National Implementation.

1.3 Conducting a self-assessment and gap analysis

Before deciding on implementing measures, consideration should be given to the conduct of a self-assessment and gap analysis of the existing legislative, regulatory and other measures against the requirements stemming from the Convention, also taking into account the biological risks faced by the State Party. Suggested resources for the conduct of a self-assessment and gap analysis are provided in Annex 3. States Parties seeking assistance for the conduct of a self-assessment and gap analysis may refer to Annex 4.

1.3.1 Purpose

Given the areas of relevance for BWC implementation, the vast majority of, if not all States Parties, have some pre-existing measures that give effect to at least some of their obligations under the Convention. They may, for example, have:

- Penal legislation that could be applied to punish certain biological weapons-related offences;
- Customs procedures to combat illicit transfer of dangerous goods; or
- Emergency management plans adopted with respect to high-risk facilities for the protection of the environment and the public.

Laboratories and research centres may also already have in place biosafety guidelines or related internal regulations, which may serve as a basis for the adoption of further measures in the area of biosecurity.

The purpose of the self-assessment and gap analysis would be to assess the measures already in place at the national level in those areas of relevance to the BWC, as well as the biological risks faced by the State Party. The authorities could then:

- Identify gaps which require new measures or the revision of existing ones to ensure the full and effective implementation of the BWC and alignment of the measures to the actual biological risks;
- Agree on priorities and actions to take in the implementation process to feed into a national plan of action (discussed below); and
- Avoid unnecessary duplication of measures across different pieces of legislation or regulations, each serving the same purposes, and address inconsistent requirements, if they exist.

1.3.2 Initial steps

Before starting the self-assessment and gap analysis, responsible officials should:

(a) Get acquainted with the scope of the necessary BWC implementing measures

This may be based on a review of the BWC's articles and the subsequent understandings reached by States Parties at BWC meetings. In this process, the officials could consider using the indicative list of BWC implementing measures (see Annex 2) and the questionnaires and other resource materials developed by some States Parties in the context of different voluntary activities (see Annex 3). A review of the working papers submitted by States Parties to BWC meetings may also provide insightful information on the measures adopted by other States Parties, as well as the implementation challenges they have faced.

(b) Obtain a good understanding of where the biological risks and threats lie

For this step and before engaging in a proper biorisk assessment (discussed below), a review of the discussions held and working papers submitted by States Parties to BWC meetings on the review of developments in the field of science and technology may be useful.

(c) Engage the identified stakeholders

All relevant governmental structures and, if appropriate, other relevant stakeholders should participate in the process, which should be multi-disciplinary and bring together legal and technical officials.

1.3.3 Main activities

(a) Assessing the level of biorisk and determining priorities

To adjust the necessary implementing measures to the national context, the self-assessment and gap analysis should take into account the State Party's characteristics and capabilities, as well as the types of risks and threats it faces, in order to assess the level of biorisk and determine priorities in the implementation process. Factors to be considered could include:

- The type and size of activities and facilities located in the country involving biological agents and toxins, and the type and quantities of biological agents and toxins involved. In particular: whether the State Party hosts Biosafety Level 4 laboratories or other facilities involving high-risk biological organisms or toxins, has a biological science research sector or biotechnology industry, or operates a biodefence programme;

- The extent of national and international transfers of BWC-relevant biological agents, toxins, items and technologies, using e.g. international or regional control lists (see Box 32 in Module IV);
- The effectiveness of the biosecurity systems in place, and the vulnerability towards a risk of diversion of the biological agents or toxins for non-peaceful purposes or otherwise posing a biorisk; and
- The State Party's security situation, also taking into account the level of security at borders and any known vulnerabilities (porous borders, piracy, presence of terrorist groups, lack of enforcement or knowledge of legislation, etc.).

(b) The identification and review of existing relevant domestic legislation, regulations and other instruments

Because the measures to be enacted for BWC implementation are cross-cutting, States Parties may already have relevant measures in place, of which they should be aware. The sectors and areas of law that may be of relevance when conducting a self-assessment are numerous and may include:

- Pre-existing legislation related to biological weapons or weapons of mass destruction;
- Penal legislation;
- Anti-terrorism legislation;
- Export control legislation;
- Strategic trade control legislation;
- Customs legislation;
- Regulations on the transportation of dangerous goods;
- Health legislation;
- Animal health legislation, including veterinary legislation;
- Environmental legislation;
- Plant health legislation, including crop legislation;
- Legislation on the control of dangerous waste;
- Food legislation;
- Workers' legislation; and
- Biosafety guidelines or other internal regulations adopted by stakeholders.

(c) The identification and review of operational functions at all governmental levels

In the conduct of the self-assessment, States Parties should also seek to identify the authorities responsible for operational functions relevant for BWC implementation. These may relate to:

- The licensing and inspection of relevant facilities and activities;
- Collection of related data;
- Border controls;
- Export controls;
- Enforcement, including judicial or administrative police powers in relation to related offences;
- Investigation and prosecution of offences;
- Oversight of research in the life sciences; and
- Mutual assistance and international cooperation in penal matters.

Obtaining a good understanding of the institutional framework in place in relation to these operational functions may serve to avoid duplication of responsibilities, ensure coordination amongst relevant authorities, and seek any possible synergies which could result in financial savings.

(d) The identification and review of measures or other actions taken at the national level for the implementation of other relevant international instruments

Such instruments may include for example:

- UN Security Council resolution 1540 (2004);
- International instruments to prevent terrorist acts, a list of which is maintained on the United Nations Office of Counter-Terrorism website at https://www.un.org/counterterrorism/international-legal-instruments, as well as regional anti-terrorism conventions;
- The Chemical Weapons Convention;
- The international control regimes on dual-use items; and
- The International Health Regulations (2005).

Relevant information on such measures or actions may already be contained in reports submitted by States Parties under related international instruments:

- The national reports on the implementation of UN Security Council resolution 1540 (2004), which are available at https://www.un.org/en/sc/1540/national-implementation/national-reports.shtml;
- The OPCW reports on the implementation of Article VII of the CWC (see the official documents from the Conference of the States Parties and from the Executive Council at https://www.opcw.org/resources/documents);
- The WHO Joint External Evaluation country reports, available at https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations.

Information on specific legislation adopted with respect to these other instruments may also be found in the legislation databases maintained with respect to each instrument. Links to such databases are provided in Annex 3. A review of such measures may help to identify synergies as well as potential conflicts with BWC implementing measures.[5]

Any such reviews should be conducted in relation to the requirements of the BWC, and lead to the identification of the areas in which measures are lacking and a determination of actions to be taken for BWC implementation purposes. In making such a determination, each State Party should establish its own priorities and determine the approach it wishes to take for BWC implementation. As discussed in Module II, there are various possible approaches. Which approach to choose may depend on a number of factors, including the structure of the existing legislative and regulatory framework as well as the type and extent of the gaps identified.

1.4 Developing a national action plan (NAP)

Based on the outcome of the self-assessment and gap analysis, States Parties could develop a national action plan (NAP) listing the steps which need to be taken to achieve the adoption of the necessary implementing measures. This plan should take into account the priorities established for the country and associate each identified action to a timeframe. It should also identify the responsible actors involved, the required resources and, as appropriate, the assistance needs.

5 For examples of potential conflicts between laboratory biosafety and laboratory biosecurity, see the *Biorisk management: Laboratory biosecurity guidance*, WHO, 2006, at https://apps.who.int/iris/bitstream/handle/10665/69390/WHO_CDS_EPR_2006.6_eng.pdf?sequence=1&isAllowed=y

States Parties' priorities as established in the NAP may vary depending on a number of factors, including the specific national or regional context, the outcome of the biorisk assessment, and the available resources.

The NAP should be prepared by, or in consultation with, all relevant stakeholders, including academia and industry, in order to secure their full commitment to the plan and the priority actions which it contains.

While a NAP is a useful tool to summarise in a structured manner the actions to be taken by the various stakeholders and measure progress in the implementation process, it should remain a living, working document requiring continuous review and adjustments, including to take stock of progress and delays, if any, and new priorities as they may emerge.

A NAP for BWC national implementing measures may be designed as a specific instrument for such a purpose, or be part of and feed into the national programme for BWC implementation or into an even broader framework, for example:

- The national action plans for the implementation of the key provisions of UN Security Council resolution 1540 (2004), which Security Council resolution 2325 encouraged all UN Member States to prepare on a voluntary basis;
- The CBRN national action plans, developed within the framework of the European Union Chemical, Biological, Radiological and Nuclear Risk Mitigation Centres of Excellence (EU-CBRN CoE) Initiative[6]; and
- The national action plans for health security (NAPHS) developed to accelerate the implementation of the International Health Regulations (IHR) core capacities and based on a One Health, all-hazards, whole-of-government approach

6 For further information, see BWC/CONF.VIII/WP.32 and BWC/CONF.VIII/WP.32/Corr.1, "A coordinated approach to enhancing bio-risk mitigation: National CBRN action plans", submitted by Côte d'Ivoire, Gabon, Georgia, Kenya, Montenegro, Philippines, Republic of Moldova, Serbia, Senegal, Uganda.

Box 6 – Additional resources for the development of a national action plan

- States Parties seeking assistance with the development of a national action plan for the implementation of Security Council resolution 1540 (2004) may submit a request to the 1540 Committee, following the procedure specified on its website at https://www.un.org/en/sc/1540/assistance/assistance-template.shtml

- National implementation action plans as developed by UN Member States for the implementation of resolution 1540 (2004) are available on the 1540 Committee's website at https://www.un.org/en/sc/1540/national-implementation/national-implementation-plans.shtml

- Guidance for the development and implementation of a NAPHS may be found in the WHO publication *NAPHS for ALL: A Country Implementation Guide for NAPHS*, available at https://www.who.int/publications/i/item/naphs-for-all---a-country-implementation-guide-for-naphs.

  For further information on the NAPHS, please refer to https://www.who.int/activities/supporting-national-implementation-of-international-health-regulations.

Sample structures for NAPs have been developed by other organisations to assist States in the fulfilment of their international obligations. For example, see below for a sample NAP produced by the OPCW for the implementation of the CWC.

Figure 2 – Sample national action plan

#	Priority objective	Action Actions which must be completed to achieve the objective	Responsible The agency responsible for the action	Partners Stakeholders whose cooperation is required	Budget Financial resources required	Timeframe When the action must be completed	Status Completed / in progress
1.							
2.							
3.							
4.							
5.							

In order to ensure the Government's commitment and to mobilise the required resources to take the actions identified in the NAP, it may be important that the plan be subject to high-level approval. It is also important to maintain continuous oversight of progress in the NAP implementation, and that the NAP be monitored and reviewed at regular intervals. The process for such monitoring and review, including the identification of the bodies or officials in charge, may be approved at the same time as the plan. If an inter-governmental body has been established and assigned responsibility for BWC implementation, such a body would in principle discharge this task.

1.5 Overview of the possible approaches to national implementation

As discussed in the Introduction, there is a wide range of national measures to implement the BWC, which operate at various levels (legislative, regulatory, etc.). There is no one single approach when deciding on how to implement the BWC and determining the type of national implementing measures to adopt.

Instead, the implementation approach may vary depending on the State Party's priorities established as an outcome of the self-assessment and gap analysis (see Module I), taking into account a number of factors, including:

- The type and size of the activities and facilities relevant to the BWC, and in particular whether the country hosts Biosafety Level 4 laboratories or other facilities involving high-risk biological organisms or toxins, has a biological science research sector or biotechnology industry, or whether the State Party operates a biodefence programme;
- The extent of and control exercised over national and international transfers of BWC-relevant agents, toxins, items, technologies and expertise;
- The emergence of infections, and capacity to respond thereto;
- The State Party's legal system, and the legal and institutional frameworks already in place in the country, including whether there is relevant legislation or regulations in force which may serve as a basis for the introduction of new requirements stemming from the BWC; and
- The human and financial resources which may be mobilised for the BWC national implementation process.

▲ BWC Meeting of States Parties at the Palais des Nations, Geneva.
Photo credit: UNOG.

For example, a Small Island Developing State may consider prioritizing the establishment of a robust transfer control regime, while the priority for a landlocked country with a large bioindustry might be quite different.

Therefore, the adoption of a phased approach, in which implementing measures are taken sequentially to address the various areas of the BWC, should be considered, particularly in States Parties with limited resources and capacity. A first set of implementing measures could, for example, consist of the establishment of prohibitions and related offences and penalties, and the basic requirements for the conduct of controlled activities, including transfers and production of relevant agents, toxins, equipment and technologies.

Other necessary implementing measures, including the details of the transfer control regime and of the biosafety and biosecurity measures, could be developed as part of a subsequent implementation phase. In that regard, States Parties may need to carefully consider, in advance, at which level – legislative, regulatory or administrative – each set of measures needs to be adopted.

1.5.1 Different approaches to BWC implementation

Based on an analysis of existing approaches to BWC implementation, States Parties generally take one of the three approaches outlined below. However, it should be noted that these are not mutually exclusive and have in fact often been combined by States Parties.

WMD or CBRN approach

Under this approach, a State Party decides to implement in one law all the obligations stemming from the relevant international instruments in the chemical, biological, radiological, and nuclear (CBRN) areas or related to weapons of mass destruction (WMD). For example, this can include UN Security Council resolution 1540 (2004), the BWC, the Chemical Weapons Convention (CWC) the Nuclear Non-Proliferation Treaty (NPT) and the Treaty on the Prohibition of Nuclear Weapons (TPNW).

Given the similarities in national implementation requirements across these international legal instruments, States Parties may find such an approach efficient, particularly if they have limited resources to implement a large number of international obligations, or if they seek to have legislative implementing measures for all related instruments adopted at once by Parliament.

While the implementing measures to be adopted in furtherance of the BWC, the CWC and the nuclear conventions have commonalities, States should, however, be mindful of the specific characteristics of nuclear, radiological, chemical and biological weapons and the distinct nature of the agents and materials relating to each category of such weapons, the differences in the facilities subject to control, as well as more generally the differences in the requirements established under each relevant instrument.

Such differences could, however, be addressed through the implementing regulations to be adopted in furtherance of a WMD or CBRN act, or other measures. Thus, while a State Party could, for example, consider it appropriate and desirable to implement the obligations stemming from UN Security Council resolution 1540 (2004) through a single act, it could adopt further specific pieces of legislation or regulations to address the specific characteristics or requirements of each category of weapons and CBRN material, and each international convention or agreement.

Box 7 – Examples of the WMD or CBRN approach[7]

This is an illustrative list of States Parties having adopted WMD or CBRN acts as their main instrument for the implementation of the BWC and relevant United Nations Security Council resolutions on WMDs:

- Cambodia: Law on the Prohibition of Chemical, Nuclear, Biological and Radiological Weapons, implemented through the Royal Decree on the Establishment of a National Authority for the Prohibition of Chemical, Nuclear, Biological and Radiological Weapons;
- India: Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005; and
- South Africa: Non-Proliferation of Weapons of Mass Destruction Act 1993, as amended, and implemented through the Declaration of Certain Biological Goods and Technologies as Controlled Goods and Control Measures Applicable to Such Goods (Government Notice No. 494 of 29 March 2019).

7 The texts of the vast majority of the instruments referenced here are accessible from the BWC Legislation Database maintained by VERTIC at https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/. To facilitate the consultation of these texts, hyperlinks are also provided.

As an alternative to the comprehensive WMD or CBRN approach, some States Parties have adopted, as stand-alone or in combination with other legislation, legislation for the purpose of implementing the BWC at the same time as the CWC.

Box 8 – Examples of combined implementation of the BWC and the CWC

This is an illustrative list of States Parties which have implemented the BWC and the CWC at the same time:

- Chile: Law N° 21.250 of 17 August 2020 on the implementation of the CWC and the BWC;
- Republic of Korea: Act on the Prohibition of Chemical and Biological Weapons and the Control of the Production, Export and Import of Specific Chemicals and Biological Agents.

▼ Under-Secretary-General and High Representative for Disarmament Affairs Izumi Nakamitsu meets Leonardo Bencini, President-designate of the Ninth Review Conference of the BWC, during a visit to the Geneva Branch of the UN Office for Disarmament Affairs. Photo credit: BWC ISU.

Box 9 – Focus on the Republic of Korea's experience

"3. To effectively prohibit and prevent the development of any biological weapons and to control the manufacture of biological agents or toxins that can be used as biological weapons, the ROK's Ministry of Trade, Industry, and Energy (MOTIE) thoroughly revised the Chemical Weapons Prohibition Act of 2006 into the Act on the Prohibition of Chemical and Biological Weapons and the Control of the Production, Export, and Import of Specific Chemicals and Biological Agents (CBWPA). In addition, the CBWPA requires the export of biological agents and toxins to abide by the Public Notice of Exportation and Importation of Strategic Items in accordance with the Foreign Trade Act.

4. The CBWPA was revised and expanded to provide a comprehensive set of rules and regulations on the prohibition and control of biological agents that had been previously scattered among various Acts, such as the Infectious Disease Control and Prevention Act, the Act on the Prevention of Contagious Animal Diseases, and the Plant Protection Act.

5. With the recent dramatic developments in biotechnology, the respective roles of government agencies, the relevant industries, and academia have become more critical for the national implementation of the BWC. The Korean government established a framework to encourage and to maintain close cooperation between government agencies and nongovernment organizations, focusing on reinforcing the national implementation of the BWC, including the effective and efficient application of the CBWPA."

Source: BWC/MSP/2020/WP.8, dated 22 November 2021, "Implementation of Articles IV and X of the Biological Weapons Convention", submitted by the Republic of Korea

Stand-alone act approach

Under this approach, a State Party adopts an act specifically dedicated to, and addressing all aspects of, BWC implementation – from the establishment of the BWC-related prohibitions and criminalisation of their violation to the establishment of the required control regimes to prevent the transfer, development, production, etc. of biological weapons.

Over the years, many States Parties have adopted a specific act for the implementation of the BWC. Not all, however, have opted for such an act to comprehensively address all aspects of the BWC. Thus, in some States Parties, such an act only incorporates the penal aspects of the BWC while the other aspects are regulated through other measures, as further discussed below.

Box 10 – Examples of specific BWC-implementation acts[8]

This is an illustrative list of States Parties which have adopted specific acts for the implementation of the BWC:

- Antigua and Barbuda: Biological Weapons Act (1975);
- Australia: Crimes (Biological Weapons) Act 1976;
- Botswana: Biological and Toxin Weapons (Prohibition) Act, 2018;
- Brunei Darussalam: Biological Weapons Act 1975;
- Czech Republic: Act No. 281/2002 Coll. of 30 May 2002 on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act, implemented through Decree No. 474/2002 Coll. of 1 November 2002 on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act, and further supplemented by Act No. 594/2004 Coll., Implementing the European Community Regime for the Control of Exports, Transfer, Brokering, and Transit of Dual-use Items (see Box 11 below);
- Fiji: Biological and Toxin Weapons Act 2011;
- France: Law No. 72-467 of 9 June 1972 prohibiting the development, production, possession, storage, acquisition and transfer of biological or toxin weapons, subsequently codified into the Code of Defence;
- Ireland: Biological Weapons Act 2011;
- Japan: Law on Implementing the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction and the Other Conventions of 8 June 1982, as amended;
- Mauritius: Biological and Toxin Weapons Convention Act 2004;
- Netherlands: Implementing Law of the Biological Weapons Convention, 1981;
- Niue: Biological Weapons Convention Act 2018;

8 The texts of the vast majority of the instruments referenced here are accessible from the BWC Legislation Database maintained by VERTIC at https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/. To facilitate the consultation of these texts, hyperlinks are also provided.

- Saint Kitts and Nevis: Biological Weapons Act 1991;
- Serbia: Law on the Prohibition of the Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction;
- Singapore: Biological Agents and Toxins Act 2005, as amended, and implemented through the Biological Agents and Toxins (Transportation) Regulations 2005, Biological Agents And Toxins (Proficiency Testing) Regulations 2008 and Biological Agents And Toxins (Exemption) Regulations 2009;
- Slovakia: Act of 28 March 2007 on the Prohibition of Biological Weapons and on Amendments and Supplements to Certain Acts;
- Trinidad and Tobago: Bacteriological (Biological) and Toxin Weapons Act 2012;
- United Kingdom: Biological Weapons Act 1974.

Box 11 – Focus on the Czech Republic's experience

"2. A key legal regulation is **Act No. 281/2002 Coll.,** on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act, which significantly contributes to the fulfilment of the commitment arising from Article IV of BTWC. Its basic principles are as follows:

(a) Creation of the supervision of the observance of the prohibition of the development, production and stockpiling and use of biological and toxin weapons,

(b) Creation of the supervision of the handling of highly hazardous and hazardous biological agents and toxins,

(c) Introduction of the recording system in the area of handling of highly hazardous and hazardous biological agents and toxins,

(d) Definition of the conditions for the handling of highly hazardous and hazardous agents and toxins, definition of inspector competencies,

(e) Imposition of sanctions for possible breach of obligations.

3. The implementing legal regulation to this Act is **Decree No. 474/2002 Coll.** A part of annexes to this Decree are a list of highly hazardous biological agents and toxins, and a list of hazardous biological agents and toxins. This Decree stipulates particulars on the keeping of records of highly hazardous and hazardous biological agents and toxins, and also lays down the requirements for the data contained in declarations, which shall be submitted by persons handling of such agents and toxins to the State Office for Nuclear Safety within the specified time.

4. Another important part of the legal system, which contributes to the fulfilment of Article III and Article IV of BTWC, is **Act No. 594/2004 Coll.,** Implementing the European Community Regime for the Control of Exports, Transfer, Brokering, and Transit of Dual-Use Items. Following the directly applicable regulation of the European Communities, this Act regulates export control of dual-use items, provision of brokering services related to dual-use items and transit while observing the international regimes, international treaties and conventions, the performance of which the Czech Republic is committed to, as well as some rights and obligations of brokers, exporters of dual-use items and other persons, who participate in the export, rights and obligations of persons transporting dual-use items from the territory of the Czech Republic to the territory of another Member State of the European Union. Furthermore, the Act regulates the control of the provision of technical support related to certain military end-uses, and rights and obligations of persons importing dual-use items to the Czech Republic.

5. To implement the Act, Annex I to the **Regulation (EU) No. 388/2012 of the European Parliament and of the Council,** amending Council Regulation (EC) No. 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, shall apply. This annex contains a list of dual-use items structured into respective categories."

Source: BWC/MSP/2012/WP.6, dated 5 December 2012, National implementation of the BTWC: compliance assessment: update, submitted by Canada, the Czech Republic and Switzerland

Multi-sectoral approach

Under the multi-sectoral approach, a State Party implements the various aspects of the BWC by building upon existing regimes and complementing, as appropriate, the provisions of, for example, penal legislation, customs and export control legislation, legislation on arms and ammunition, health legislation or legislation on the protection of the environment. Thus, the BWC is implemented through various pieces of legislation each addressing different aspects of the Convention.

Under this approach, a State Party may, for example, consider addressing biosecurity separately from the penal and transfer control aspects, and adopt a global approach with respect to biosafety and biosecurity by seeking synergies with other international instruments such as the International Health Regulations (IHR) or the Convention on Biological Diversity and the Cartagena Protocol.

Equally, for the implementation of Article III of the Convention, a State Party may consider relying on existing rules in the area of import/export control and extend the general legal framework established to regulate the transfer of dual-use or strategic goods to cover the BWC-relevant biological agents, toxins, equipment, means of delivery and technologies.

Amongst others, Brazil, Bulgaria, Canada, China, Cuba, Jordan and Switzerland have followed this approach.

Box 12 – Focus on Canada's experience

"42. Canada has several pieces of legislation in place to see to the non-proliferation of biological weapons as required by the BTWC and biosecurity and the non-proliferation of biological materials. Each law covers a piece of the biosafety/biosecurity landscape and, all together, allows Canada to meet its obligations under the Biological and Toxin Weapons Convention and the United Nations Security Council Resolution 1540 (2004). This legislation enforces biosafety, biosecurity, and non-proliferation of biological materials in Canada. Laws are separated into two sections: main relevant legislation, that have a more direct effect on biosecurity and non-proliferation, and other legislation of relevance, that have a limited impact on these issues.

[…]

1. Main Relevant Legislation

45. Main Relevant Legislation

(a) Human Pathogens and Toxins Act (partially in force)

(b) Human Pathogens Importation Regulations

(c) Health of Animals Act

(d) Plant Protection Act

(e) Export and Import Permits Act

2. Other Legislation of Relevance

46. Other Legislation of Relevance

(a) Canadian Environmental Protection Act

(b) Department of Public Safety and Emergency Preparedness Act/ Emergency Management Act

(c) Feeds Act

(d) Pest Control Products Act

(e) Fertilizers Act

(f) Hazardous Products Act

(g) Quarantine Act

(h) Transportation of Dangerous Goods Act

(i) Chemical Weapons Convention Implementation Act

(j) Customs Act / Canada Border Services Agency Act

(k) Criminal Code of Canada

(l) Biological and Toxins Weapons Convention Implementation Act [9] (not in force)".

Source: BWC/MSP/2012/MX/WP.17, dated 3 August 2012, National Implementation of the BTWC Compliance Assessment, submitted by Canada and Switzerland

9 The Biological and Toxins Weapons Convention Implementation Act was repealed before coming into force (see https://laws-lois.justice.gc.ca/pdf/B-5.3.pdf).

Box 13 — Focus on Jordan's experience

Jordan became a State Party to the BWC in 1975. Jordan has implemented the BWC through, mainly, its penal code, as well as its legislation on export control, environmental protection and public health.

- Penal Code
- Customs Law No. 20 of 1998, as amended
- Law No. 21 of 2001 on Import and Export, as amended
    - o Regulations No. 114 of 2004 on Export and Import Licenses
    - o Regulations No. 1 of 2009 on
    - o Export and Re-Export of Dual-Use Materials
    - o Import Instruction No. 1 of 2012, as amended
    - o Finance Minister's Decision 1991 on Specified Prohibited Goods
    - o Instructions for Exporting and Re-Exporting Dual-Use Materials (2019)
    - o List of Jordanian Controlled Items Subject to Non-Automatic Export Licence (2018), and National List of Dual-Use Materials Subject to Non-Automatic Export/Re-Export Licence
    - o Revised Instructions for Transit Goods No. 5 of 2006
- Public Health Law No. 47 of 2008
    - o Ordinance on the Licensing of Private Medical Laboratories No. 30 of 2003
    - o Bylaw on Private Hospitals of 2014
    - o Instructions on Managing Medical Wastes of 2001
    - o Instructions on Packaging and Transportation Requirements for Biological Materials and Isolates of 2009
- Law on Conducting Pharmaceutical Studies of 2001
- Law on Protection of the Environment No. 6 of 2017
    - o Bylaw for Managing the Protection of the Environment (2018)
    - o Bylaw for the Protection of Soil from Contamination (2005)
    - o Bylaw for the Protection of Air from Contamination
    - o Bylaw for Managing Solid Wastes (2005), under revision
    - o Bylaw for Managing Hazardous Materials and Wastes (2020)
- Terrorism Prevention Law 2014
- Municipalities Law (2015), including provisions on public health and prevention of spreading of outbreaks, and on the locations of public hospitals and medical centres and facilities

1.5.2 Combining the implementation approaches

As outlined above, there is no preferable approach to follow for the implementation of the BWC, and States Parties may be inclined to select one or other depending on their specific circumstances, including the extent of the gaps identified as an outcome of the self-assessment and gap analysis conducted (see Module I) and the priorities established at the national level.

For example, if the results of the self-assessment and gap analysis indicate that robust measures are already in place for the control of transfers of dual-use items, the State Party could consider building upon the existing legislation and ensuring that the list of items and technologies subject to such controls encompass the agents, toxins and related items and technologies relevant to the BWC.

A State Party which is yet to fully implement the BWC, as well as other international disarmament and non-proliferation instruments which have features in common with the BWC, for example the Chemical Weapons Convention, could be inclined to implement all its obligations stemming from these instruments in one act. Moreover, the approaches mentioned above are not mutually exclusive, and many States Parties have in fact combined them.

Thus, in the years immediately after the entry into force of the BWC in 1975, several States Parties adopted a specific act to address the penal aspects of the Convention, while other aspects of the BWC were addressed through other measures, which evolved over time. States Parties having such a combination of acts in place include, for example, Australia, Finland, France, the United Kingdom, and the United States.[10]

Such a combined approach acknowledges that the type and scope of the BWC national implementation measures to be taken by States Parties are not static but are evolving as the risks and international and national requirements evolve in view of the emergence of new biorisks and new scientific and technological developments.

10 The list of the implementing measures adopted by these States Parties may be found in their respective CBM submissions available from the CBM portal at https://bwc-ecbm.unog.ch/group/ecbm-portal.Texts of implementing measures may be accessed from the BWC Legislation Database maintained by VERTIC at https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/

States Parties with implementing measures in place may, therefore, consider it necessary at some point to review their legal implementing framework to ensure it is still fit for purpose and, depending on the outcome of such review, revise the existing framework and adopt supplementary pieces of legislation or regulations.

Box 14 – Focus on Australia's experience

Some of the legal and regulatory implementing measures adopted by Australia relevant to the BWC include:

- Crimes (Biological Weapons) Act 1976, as implemented by the Crimes (Biological Weapons) Regulations;
- Chemical Weapons (Prohibition) Act 1994 and associated regulations;
- Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and associated regulations;
- Customs Act 1901 and Customs (Prohibited Exports) Regulations 1958;
- Biological Control Act 1984 and associated regulations;
- National Health Security Act 2007;
- Security Sensitive Biological Agent Standards;
- Biosecurity Act 2015 and associated regulations.
- Gene Technology Act 2000 and associated regulations;
- Therapeutic Goods Act 1989 and associated regulations;
- Defence Trade Controls Act 2012 and associated regulations.

Source: 2020 CBM submission

MODULE II - GETTING STARTED

This Module outlines actions to support the drafting and legislative process, and briefly presents possible complementary measures for the full and effective implementation of the BWC. It also explains the distribution of roles and responsibilities for administering and enforcing the BWC at the domestic level.

2.1 Starting the drafting process

The exact distribution of the law-making power at the national level varies among States Parties. However, even in those States Parties which have vested the legislative power with parliaments, in practice, the initiative is often with the executive which oversees drafting new laws.

At the time of initiating the drafting process, the implementation approach has normally been decided, and the governmental entities responsible for taking action towards the adoption of the necessary legislative or regulatory implementing measures have been designated. There may still remain the need to designate the person or group of persons responsible for developing the content and drafting the actual text of the measures.

Designating several drafters may be necessary in particular where an inter-governmental body has been established to be in charge of BWC implementation and coordinate the necessary actions, or where it has been decided to build on existing legislation and/or adopt a multi-sectoral approach for BWC implementation.

The drafters should preferably be acquainted with the requirements flowing from the BWC and/or the legislation or regulations governing the relevant subject areas, and be provided with all materials reviewed in, and the results of, the self-assessment and gap analysis, in order to minimise redundancy in work and save resources. The review of these documents will also help to understand the rationale and purpose for the proposed measures and assist in developing the explanatory note generally accompanying the draft text when it is submitted for governmental approval or introduced to parliament.

As a starting point in the elaboration of the draft, the legislative drafter(s) may consider using model provisions, checklists and/or the implementing measures of other States Parties as reference points. It is also important in this process that the drafter(s) closely work and coordinate with technical experts, in order to design fit for purpose measures.

Consultation with relevant stakeholders as previously identified should continue, by circulating drafts and seeking input where necessary, including from non-governmental stakeholders such as academia and industry. A broader consultation process to include the views of the public could also be considered.

Box 15 – Seeking assistance for BWC implementation

The Sixth Review Conference urged "States Parties with relevant experience in legal and administrative measures for the implementation of the provisions of the Convention, to provide assistance on request to other States Parties. The Sixth Review Conference also encouraged such initiatives on a regional basis."[11] The Seventh and Eighth Review Conferences further encouraged "those States Parties, in a position to do so, to provide assistance, upon request, to other States Parties."[12]

In addition to the assistance that States Parties may extend to each other in the process of developing the implementing measures, there is also a wide range of legislative assistance programmes of which States Parties may avail. These programmes may have been developed for the specific purpose of BWC implementation or to support the implementation of other international instruments which have significant synergies with the BWC, in particular UN Security Council resolution 1540 (2004). A list of such programmes is provided in Annex 4.

11 See BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraph 16.

12 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 14, and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 14.

Moreover, VERTIC has developed various tools such as an online drafting assistant, model acts and guidelines which States Parties could find useful to use when starting the drafting process. These can be accessed from the VERTIC website at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-assistant/ and https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/.

At the regional level:

- CARICOM has developed a Model Act to implement UN Security Council resolution 1540 (2004) and treaty obligations relating to the prevention and proliferation of nuclear, chemical and biological weapons (Strategic Trade Control Act);

- A "Regional biosafety and biosecurity legal framework" is being developed by the Africa Centres for Disease Control and Prevention (Africa CDC).

Reviewing the range of measures adopted by other States Parties may also serve as a useful reference point when initiating the drafting of measures. For this purpose, States Parties could refer to:

- The submissions by other States Parties in their Confidence-Building Measures (CBM), in particular Form E, as available on the electronic CBM facility at https://bwc-ecbm.unog.ch.

- The BWC Legislation Database maintained by VERTIC and accessible at https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/

- The approved 1540 Committee matrices, which reflect the measures that UN Member States have taken for the fulfilment of their obligations under UN Security Council resolution 1540 (2004). These are available on the 1540 Committee website at https://www.un.org/en/sc/1540/national-implementation/1540-matrices/committee-approved-matrices.shtml

Additional references to legislation databases and other resources are provided in Annex 3.

2.2 Legislative process

In States Parties having vested the legislative power with parliament, once a draft legislative text is ready and has obtained all required approvals at the governmental level, the next step will generally be its submission for parliamentary adoption. In order to ensure the smooth and swift adoption of the implementing law, it is important to engage with parliamentarians at an early stage of the implementation process, to:

- Raise awareness about the State Party's international obligations while emphasising the national benefits of BWC implementation;
- Provide background information, clarify the technical aspects of the legislative measures and respond to questions, as may be required, so as to render the law intelligible by relating its content to clear and specific objectives;
- Foster a shared sense of ownership and responsibility towards the adoption of implementing measures; and
- Facilitate the inclusion of the draft law into the legislative agenda, including by possibly identifying whether the BWC implementing law could be included as part of a package of related laws to be considered simultaneously by the Parliament.

Box 16 – Seeking assistance to promote BWC implementation amongst Parliamentarians

Campaigns and activities conducted by organisations such as Parliamentarians for Global Action (PGA) and the Inter-Parliamentary Union (IPU) could be useful to promote BWC implementation amongst parliamentarians. For more information, please refer to:

- The PGA Campaign to Promote the Universality and Implementation of the BWC and Implementation of UN Security Council resolution 1540 (2004).[13] See in particular https://www.pgaction.org/ips/bwc.html/. See also the *Handbook to Promote International Legislative Frameworks Addressing the Threats Posed by Weapons of Mass Destruction & Promotion of Bio-Risk Management Best Practices*, available in Arabic and English at https://www.pgaction.org/resources-for-parliamentarians.html#bwc/

13 Including e.g.: the Virtual Workshop with Malaysian and Indonesian Parliamentarians to

- The IPU website, which contains information on the IPU peacebuilding activities. See in particular at https://www.ipu.org/our-impact/peacebuilding/.

- The handbook *Assuring our Common Future: A guide to parliamentary action in support of disarmament for security and sustainable development*, published by Parliamentarians for Nuclear Non-proliferation and Disarmament (PNND), is also a useful reference tool to educate and engage parliamentarians about the implementation of the BWC. The handbook is available at: https://disarmamenthandbook.org

2.3 Taking regulatory measures

Rarely will it be the case that the adoption of legislative measures alone will be sufficient to ensure full national implementation of the BWC, and the adoption of complementary regulations will most likely be required to specify the obligations and control regimes established by law, or to designate and empower the relevant authorities. Such complementary regulations may include import/export control regulations or the establishment of a domestic inspection system for relevant facilities.

Therefore, as may be required by the constitutional processes of each State Party, the implementing law may need to include a legal basis empowering the government to adopt such complementary implementing regulations.

In some States, the type of measures to be set forth in law or regulations is specified in the constitution. Some other considerations may also guide States Parties when deciding in which instrument to set forth specific provisions. Thus, States Parties may wish to maintain a certain flexibility to review the adequacy of the measures adopted, and therefore may prefer to set forth the details of such measures in regulations, and not in legislation in order to ease the process for future amendments. This may, for example, be relevant with respect to those provisions setting forth:

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address challenges of COVID-19 through Implementation of Existing International Biosecurity and Biosafety Frameworks held in September 2020; the Regional Caribbean Workshop on Biological Security Frameworks held in October 2019; and the Regional Caribbean Parliamentary Workshop to Promote Universality and Implementation of the Biological Weapons Convention and Implementation of UN Security Council Resolution 1540 (2004) held in April, 2019.

- Responsibilities for establishing the composition of specific bodies assigned a role in BWC implementation;
- The national list of controlled biological agents, toxins, weapons, equipment, means of delivery, and technologies;
- The details of the licencing regime or annual reporting requirements, such as application process, timelines, etc.; or
- The specific physical protection measures to be adopted for BWC-relevant biological agents and toxins.

2.4 Taking additional complementary measures

There is a broad range of measures beyond legislative and regulatory measures which may foster the implementation of the Convention. Several Review Conferences have thus noted the value of national implementation measures to promote: the implementation of voluntary management standards on biosafety and security; the voluntary development, adoption and promulgation of self-regulatory mechanisms such as codes of conduct; and the development of educational and outreach programmes to raise awareness amongst relevant professionals about the BWC and its embedded obligations, as well as the risks posed by relevant agents and toxins.[14]

The way such complementary measures are implemented or applied is dependent on the particular situation of each State Party.

2.4.1 Voluntary management standards

A standard is generally developed to respond to a request from industry or other stakeholders, which will subsequently voluntarily subject themselves to its provisions and seek certification of compliance from an accredited conformity assessment body.

14 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 13.b to e; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 13.b to e; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraphs 14-15; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article IV, paragraphs 3-4; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article IV, paragraph 3; BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article IV, paragraph 4.

Box 17 – Biorisk management standards

In 2019, the International Organization for Standardization (ISO) issued the first international standard for a biorisk management system: *ISO 35001:2019 Biorisk management for laboratories and other related organisations*. This standard defines the requirements and provides guidance for laboratories or any other organisation which works with, stores, transports, or disposes of hazardous biological materials, to identify, assess, control, and monitor the risks associated with such materials. This document is intended to complement existing international standards for laboratories. For more information, please refer to the ISO website at https://www.iso.org/standard/71293.html

The WHO and regional organisations such as the European Committee for Standardization (CEN) have also developed scientific and technical guidance for biorisk management. More information can be found in Module V.

2.4.2 Codes of conduct

Codes of conduct may serve to raise awareness about the BWC, and help relevant professionals to fulfil their legal, regulatory and professional obligations and ethical principles. With respect to scientific research activities, codes of conduct may assist in preventing the misuse of dual-use research while ensuring that research for peaceful purpose is not hampered. Their adoption is also relevant to promote biosafety and biosecurity in laboratories and other facilities handling biological agents and toxins. In that regard, they should apply not only to scientists, but to all those involved in scientific activity, including managers and technical and ancillary staff.

The 2005 Meeting of States Parties, under its mandate to discuss and promote common understanding and effective action on the content, promulgation and adoption of codes of conduct for scientists, recognised inter alia that:

- Codes of conduct should reflect the provisions of the BWC and contribute to national implementation measures;
- A range of different approaches exist to develop codes of conduct in view of differences in national requirements and circumstances;
- Codes of conduct should avoid impeding scientific discovery, placing undue constraints on research or international cooperation and exchange for peaceful purposes; and

- Science should be used for peaceful purposes only but has the potential to be misused in ways that are prohibited by the BWC, and therefore codes of conduct should require and enable relevant actors to have a clear understanding of the content, purpose and reasonably foreseeable consequences of their activities, and of the need to abide by the obligations contained in the BWC.

On the content of codes of conduct, States Parties agreed on the importance of codes of conduct being:

- Compatible with national legislation and regulatory controls and contributing to national implementation measures;
- Simple, clear and easily understandable both to scientists and to wider civil society;
- Relevant, helpful and effective for guiding relevant actors in making decisions and taking action in accordance with the purposes and objectives of the BWC;
- Sufficiently broad in scope; and
- Regularly reviewed, evaluated for effectiveness, and revised as necessary.

Over the years since 2005, States Parties have regularly shared national experiences and proposals for such codes of conduct. For example:

- A summary of codes of conduct referring to biological and toxin weapons, as they existed as of April 2005, was provided by the BWC Secretariat in the background paper BWC/MSP/2005/MX/INF.1. Information contained therein was updated for the 2008 Meeting of Experts, in BWC/MSP/2008/MX/INF.2.
- At the 2008 Meeting of Experts, the Netherlands shared its national experience on the development of a national Code of Conduct for Biosecurity, directed at universities and research institutes, by the Royal Netherlands Academy of Arts and Sciences.[15] This code of conduct is available at https://biosecurity.fas.org/resource/documents/IAP%20-%20Biosecurity%20code%20of%20conduct.pdf
- At the 2014 Meeting of States Parties, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Italy, Mexico and Spain submitted a proposal for a scientific practice code of conduct directed at improving the custody of biological agents and the vectors thereof on the part of the scientific community that works with biological agents and toxins.[16]

15 See BWC/MSP/2008/MX/WP.8, "Development on a Code of Conduct on Biosecurity", submitted by the Netherlands.

16 See BWC/MSP/2014/WP.6, "Código de Conducta para Científicos", submitted by Chile,

- At the Eighth Review Conference in 2016, China and Pakistan submitted a proposal for the development of a model code of conduct for biological scientists. A model code, in Chinese and English, was enclosed to serve as a basis for further discussion.[17]
- At the same Review Conference, Cuba made available the Code of Professional Ethics for Science Workers in Cuba.[18]
- At the 2020 Meeting of Experts on Review of Developments in the Field of Science and Technology Related to the Convention, China and Pakistan submitted a working paper, co-sponsored by Brazil, presenting "The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists".[19] The Guidelines have since been endorsed by the InterAcademy Partnership and are available in Arabic, Chinese, English, French, Russian and Spanish at https://www.interacademies.org/news/iap-endorses-tianjin-biosecurity-guidelines

Other examples of codes of conduct, including for academia and industry organisations, as well as the government in the area of biosafety and biosecurity, can be found on the Virtual Biosecurity Center's website at https://www.virtualbiosecuritycenter.org/codes-of-ethics/.

Box 18 — Focus on Indonesia's experience

"4. As an attempt to strengthen national measures to prevent the development and production of biological weapons as obligated under the Biological Weapons Convention, the Indonesian Academy of Sciences (AIPI) launched the Indonesian Code of Conduct on Biosecurity on 26 May 2015, coinciding with the Silver jubilee of the Academy. The Code of Conduct contains key components to address dual use research, including awareness raising, safety and security, education and information, accountability and oversight, as well as best practices on bio-risk management.

Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Italy, Mexico and Spain.

17 See BWC/CONF.VIII/WP.30*, "Proposal for the development of a model code of conduct for biological scientists under the Biological Weapons Convention", submitted by China and Pakistan.

18 See BWC/CONF.VIII/WP.2, "Code of Professional Ethics for Science Workers in Cuba", submitted by Cuba.

19 For more information see https://undocs.org/BWC/MSP/2020/MX.2/WP.6 and https://undocs.org/BWC/MSP/2020/MX.2/WP.6/Corr.1.

5. Since 2009, AIPI, together with the Royal Netherlands Academy of Arts and Sciences (KNAW) and U.S. National Academy of Sciences (NAS) held a series of events related to Biosecurity. In August 2014, AIPI, KNAW and NAS co-organized a Biosecurity workshop that took place in the context of the 9th ASEAN Science and Technology Week. The aim of the workshop was to raise biosecurity awareness in relevant institutions, academies and industry in ASEAN states, and to share experiences and lessons for education and awareness raising in biosecurity.

6. Recognizing the importance of sharing best practices on biosecurity, and as follow-up to the launch of the Code of Conduct on Biosecurity, the Indonesian Academy of Sciences, together with NAS, co-organized a follow-up workshop in August 2015. The workshop was based on the experience of the NAS and international partners in the Middle East/North Africa (MENA) and South/Southeast Asia in developing networks of faculty that teach biosecurity using 'active learning' methods. The discussion that took place in the workshop provided useful insights on the implementation of the Code of Conduct. In this regard, the Indonesian Academy of Sciences, together with other relevant institutions, will continuously promote the implementation of the Code of Conduct."

Source: BWC/MSP/2015/MX/WP.19, dated 13 August 2015, "National Measures to Address Dual Use Research", submitted by Indonesia, Malaysia, Netherlands and the United States of America

2.4.3 Outreach and education

The contributions that can be made by universities, non-governmental organisations and industry to the implementation of the BWC are also very important, in particular to raise awareness about the BWC, the risks posed by BWC-relevant biological agents and toxins, and the legal obligations arising from the Convention.

The 2008 Meeting of States Parties recognised the importance of ensuring that those working in the biological sciences are aware of their obligations under the BWC and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and are encouraged to take an active role in addressing the threats posed by the potential misuse of biological agents and toxins as weapons, including bioterrorism. Moreover, the Meeting agreed on the value of education and awareness programmes that, among others, would:

- Explain the risks associated with the potential misuse of the biological sciences and biotechnology;
- Cover the moral and ethical obligations incumbent on those using the biological sciences;
- Provide 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; and
- Address 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.[20]

Several Review Conferences have urged the inclusion of information on the BWC and the 1925 Geneva Protocol in medical, scientific and military educational materials and programmes. They also urged States Parties to promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the BWC and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention.[21]

Calls for awareness-raising and education for life scientists on dual-use research and biosecurity issues have become a focus of attention and action for States Parties. Some universities have undertaken significant efforts to develop dedicated education programmes for life scientists. In various universities and other institutions, biosecurity is also part of the education of students and researchers in the life sciences. States Parties could consider encouraging and promoting education institutions to include dedicated training in undergraduate and graduate curricula, as well as adjusting the research grant allocation system to reward dual-use risk minimization.

20 See BWC/MSP/2008/5, Report of the Meeting of States Parties, paragraph 26.

21 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 13(d); BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 13(d); BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraph 14; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article IV, paragraphs 3 and 4; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article IV, paragraph 3; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article IV, paragraph 4.

Outreach and education activities designed as a shared responsibility of both governments and the academic and scientific communities, could benefit from collaborative and collegial efforts. Scientists engaged in education and awareness-raising efforts may also contribute to maintain the State Party's awareness of new science and technology developments that have potential for uses contrary to the Convention, hence assisting in monitoring and maintaining the adequacy of national implementing measures.

Box 19 – Awareness-raising and e-learning tools and initiatives

Various States Parties and organisations have developed e-learning tools on biological weapons, biosecurity and related areas. A comprehensive listing of such tools and initiatives is contained in a 2018 report by the US National Academies of Science, Engineering and Medicine on the *Governance of Dual Use Research in the Life Sciences*.[22] Some selected tools include:

- The Public Health Agency of Canada (PHAC) has developed an e-leaning portal providing free online courses on laboratory biosafety and biosecurity, as well as health emergency material. Available at https://training-formation.phac-aspc.gc.ca/?lang=en/.
- The EU Non-Proliferation Consortium's e-learning unit on biological weapons, available at https://nonproliferation-elearning.eu/learningunits/biological-weapons/, aims to introduce students to the technical, historical, political and legal dimensions of biological weapons.
- The Federation of American Scientists has produced a series of case studies in dual-use biological research. The case studies illustrate the implications of "dual-use" biology research by featuring different researchers who have done dual-use research. The case studies are available at https://fas.org/biosecurity/education/dualuse/index.html
- The United Kingdom financed the development of an e-learning course, "Next Generation Biosecurity: Responding to 21st Century Biorisks", developed by the University of Bath and Biosecure which is available at https://www.futurelearn.com/courses/biosecurity

22 See US National Academies of Science, Engineering and Medicine, *Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight. Proceedings of a Workshop*. Available at https://www.interacademies.org/sites/default/files/publication/governance_of_dual_use_research.pdf

2.4.4 Information sharing

Information sharing plays an important role in strengthening BWC national implementation. In addition to the value of sharing scientific and technological knowledge, sharing best practices and experiences including challenges experienced in national implementation, exchanging information on the enforcement of national legislation, exploring possible ways to strengthen national institutions and coordination among national law enforcement institutions, may also contribute to furthering the implementation of many BWC obligations.

Information on States Parties' experiences in implementing the BWC may be found in the official documents produced for BWC meetings, available at https://meetings.unoda.org. Information on experiences, lessons learned, and effective practices in the areas covered by UN Security Council resolution 1540 (2004) is provided on the 1540 Committee's website at https://www.un.org/en/sc/1540/national-implementation/experiences-shared-lessons-learned-and-effective-practices.shtml

2.5 Distribution of roles and responsibilities for administering and enforcing the BWC at the domestic level

Unlike the Chemical Weapons Convention, the BWC itself does not require States Parties to designate or establish a "National Authority" or a regulatory body to administer the implementing measures adopted at the national level and monitor the State Party's compliance with the obligations stemming from the Convention.

However, the Sixth Review Conference encouraged States Parties to designate a national focal point, also referred to as a national point of contact, for coordinating the national implementation of the Convention and communicating with other States Parties and relevant international organisations.[23] This has been reaffirmed by subsequent Review Conferences.[24] States Parties have taken differing approaches to the placement of their designated national points of contact.

23 See BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraph 18.

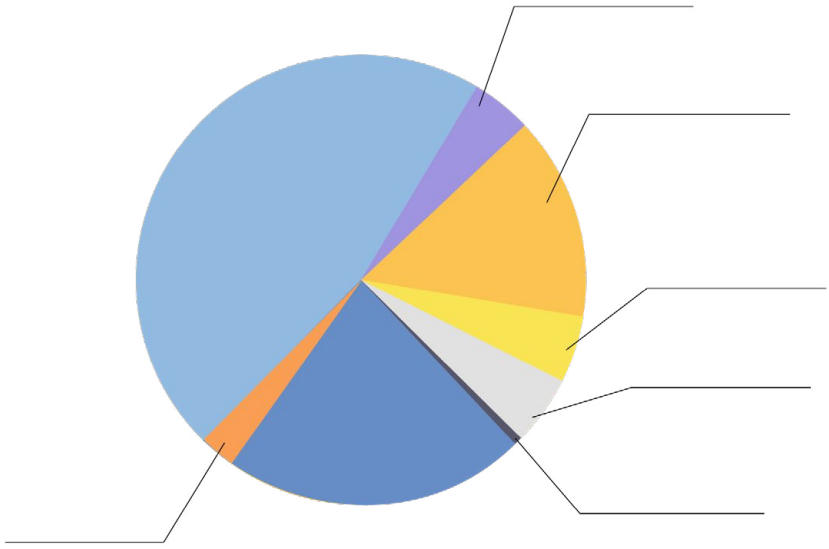
24 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 15; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 15.

Box 20 – Notification of the national point of contact

Upon designation or in case of change in the designation of the national point of contact, States Parties should notify the BWC Implementation Support Unit (ISU), using the National Contact Point Information Form at https://front.un-arm.org/wp-content/uploads/2020/12/BWC-national-contact-point-nomination-form.pdf. The contact details of all designated National Contact Points are available to all States Parties on a separate, restricted access page. Further information can be found at https://www.un.org/disarmament/biological-weapons/national-implementation.

Some States Parties have only entrusted the point of contact with acting as liaison with other States Parties and the ISU. They have generally placed the point of contact within the Ministry of Foreign Affairs. Others have entrusted the point of contact with the broad task to coordinate, promote and ensure adoption of the necessary implementing measures, as well as to oversee BWC national implementation. They may thus have designated the lead ministry or governmental agency for the implementation of the BWC as point of contact, or established an intergovernmental body to act as such, supported by a secretariat to be hosted in one of the governmental entities represented.

Figure 3 – Designation of national points of contact



As discussed in Module I, because BWC implementation is of relevance to numerous governmental bodies and requires the involvement of others such as biosafety associations, universities and industry, establishing appropriate coordination and consultation mechanisms with all relevant stakeholders is critical. Such consultations will be key to the development of implementing measures appropriately responding to the country's specific situation. They will also be essential to ensuring the smooth enforcement of such measures once adopted, in particular as various governmental authorities may be in charge of administering different aspects of the BWC implementing measures.

States Parties are free to develop their own institutional arrangements for BWC implementation and the administration of the measures taken to implement it. The determination of the most appropriate institutional arrangements is country-specific, and depends on various factors, such as the State Party's constitutional organisation (unitary, federal), the existing institutional frameworks, the State Party's chosen approach for the national implementation of the Convention (see Module I), and ultimately what each State Party may respectively deem the most appropriate organisational structure for itself.

States Parties may opt for a centralised structure, whereby one entity (sometimes referred to as the "National Authority") assumes all responsibilities and functions related to BWC implementation. These can include collecting all data and acting as national point of contact with other States Parties and the ISU, as well as in some cases the responsibility to act as the licensing authority for regulated activities and facilities. Some States Parties have even further centralised their institutional structure by designating one entity to oversee implementation of several international instruments, as is the case for example in Cambodia[25], Cuba (see Box 21), the Czech Republic, Nigeria (see Box 22), Qatar[26], Senegal[27], and South Africa (see Box 23).

25 Cambodia has established the National Authority for the Prohibition of Chemical, Nuclear, Biological and Radiological Weapons to serve as national central point for effective liaisons with other organisations and States Parties and to control and prohibit the proliferation of CBRN weapons. The text of the Royal Decree establishing the National Authority is accessible from the VERTIC website at https://www.vertic.org/media/National%20Legislation/Cambodia/KH_Law_Prohibition_CBRN_Regulations.pdf

26 Qatar has established the National Committee for the Prohibition of Weapons as a standing committee of the Ministry of Defence responsible for all matters relating to international disarmament treaties (source: BWC/CONF.VIII/INF.2, dated 21 October 2016, Compliance by States Parties with their obligations under the Convention, Background information document submitted by the Implementation Support Unit).

27 Senegal has established a National Commission for Nuclear, Biological and Chemical

Box 21 – Focus on Cuba's experience

By Agreement No. 4728/2003, the Executive Committee of the Council of Ministers designated the Ministry of Science, Technology and the Environment as the national authority for the BWC.

Pursuant to Decree Law 190/1999 on Biological Safety,[28] adopted for the implementation of the BWC as well as the Convention on Biological Diversity, the Ministry of Science, Technology and the Environment is the state agency in charge of developing, implementing and monitoring the national policy on biological safety. For this purpose, in coordination with the bodies and competent state agencies, it has the following functions and attributions:

a) Assess, guide the risk management and approve field trials or research and releases into the environment of biological agents and their products, organisms and their fragments with genetic information, independently of the risk group to which they may belong;

b) Organise, direct and conduct the inspections of facilities and all national areas where biological agents and their products, organisms and their fragments with genetic information are used or released;

c) Grant, suspend and revoke authorisations for carrying out activities related to the use, research, testing, production, release, import and export of biological agents and their products, organisms and their fragments with genetic information;

d) Establish classifications regarding:

- The organisms that are released into the environment taking into account their origin and the risk they pose for human health and the environment,
- The biological agents that affect humans, animals and plants and their distribution in risk groups,
- The facilities that use biological agents and their products, organisms and their products with genetic information.

Weapons. The text of the decree establishing this National Commission is accessible from the VERTIC website at https://www.vertic.org/media/National%20Legislation/Senegal/SN_Decret_2002-839_Commission_des_Armes_Nucleaires_biologiques_chimiques.pdf

28 The text of this Decree Law was published in the Official Gazette No. 7 of 15 February 1999, accessible from https://www.gacetaoficial.gob.cu/es/gaceta-oficial-no007-ordinaria-de-1999. It is also available from the BWC Legislation Database maintained by VERTIC.

e) Establish mechanisms for the study, assessment and management of the risks of the release into the environment of biological agents and their fragments with genetic information and the procedures to control, mitigate and treat dangerous biological wastes.

f) Establish the National System of Accountability and Control of biological and toxin agents and organisms that will be released into the environment;

g) Oversee and carry out the verifications at the containment barriers existing in the facilities that handle biological agents and organisms;

h) Arrange the total or partial closing of facilities that handle biological agents and organisms if these facilities do not have safety measures in place and pose risks for human health and the environment;

i) Study, assess, organise, coordinate, promote, participate and perform, as the case may be, all activities derived from the responsibilities and functions assigned to Cuba as State Party to international conventions in the area or in relation thereto;

j) Appoint reference centres from different bodies and institutions according to their technical and scientific conditions and specify the functions to be developed in coordination with them;

k) Adopt the necessary measures to prohibit, prevent and control the development, production, stockpiling, acquisition or retention of:

- Biological agents and toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes,
- Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;

l) Establish proper procedures for the transfer, handling and use of organisms that may have negative effects for the conservation and sustainable use of biological diversity, particularly agriculture products;

m) Others assigned by the state and the government.

Moreover, Decree-Law 10/2020 on the National Regulatory Authorities[29] further establishes the rules for the creation of the National Regulatory Authorities in Cuba, and the regulation of their operation and organisation. The Office of Regulation and Environmental Safety of the Ministry of Science, Technology and the Environment is designated as one such Authority in the

29 The text of this Decree-Law was published in the Official Gazette N. 65 of 18 September 2020, and is available, in Spanish, at https://www.gacetaoficial.gob.cu/sites/

area of, amongst others, the biological, chemical, nuclear, radiological safety and the protection of the environment against contamination. Under the Decree-Law, the National Regulatory Authorities have, inter alia, the following functions within their scope of competence:

- Prepare and propose the applicable legal provisions for the protection of the health, safety, environment and other areas determined by the Government in the field of technology.
- Issue specific provisions, procedures and regulations, and oversee and monitor their compliance, as well as with the established regulatory requirements, as well as take measures in case of breach.
- Grant, modify, suspend, revoke or renew, the authorisations.
- Conduct inspections to verify compliance with the legislation.
- Establish procedures in order to determine, inter alia, the need to adopt or modify regulations and technical provisions, and to systematically review regulations and assess their impact, in order to determine if they meet their objectives effectively and efficiency;
- Establish cooperation with the National Standardization Office to guarantee the use of the Cuban standards, and cooperation and exchanges with their international counterparts or other national authorities.
- Participate in investigations independently or with other state bodies, in the case of serious accidents or emergency situations.
- Other functions, such as to: implement international legal instruments in force for Cuba, and systems of accounting and control of materials or substances regulated at the international level, known as safeguards systems; respond to emergency situations; participate in programmes of instruction and information to the population on aspects of interest in their area of competence; promote and manage research programs, and related scientific and technical services and projects; advise the courts, attorney general of the Republic, competent bodies in criminal prosecution and the Comptroller General of the Republic; encourage the introduction of risk analysis and evaluation techniques; participate in national education and training programmes; and account for the different international obligations contracted and required to ensure the protection of health, the environment and other specific areas.

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Box 22 – Focus on Nigeria's experience

In October 2003, the Government directed the National Authority on Chemical Weapons Convention (NACWC) to take on the additional responsibility of coordinating the national implementation of the BWC in Nigeria, thus establishing the National Authority as the focal point for both the CWC and BWC. The National Authority was consequently renamed the National Authority on Chemical and Biological Weapons Conventions (NAC&BWC).

The Political and Economic Affairs Office of the Office of the Secretary to the Government of the Federation (OSGF) serves as the Secretariat of the NAC&BWC. Leadership in the implementation of the CWC and BWC is provided by an Inter-Ministerial Committee comprising 36 members, representing the following entities: NAC&BWC; Ministry of Defence; Ministry of Foreign Affairs; Federal Ministry of Science and Technology; Federal Ministry of Environment; Federal Ministry of Education; Federal Ministry of Petroleum Resources; Federal Ministry of Justice; Federal Ministry of Health; Federal Ministry of Information and Culture; Federal Ministry of Industry, Trade and Investment; Federal Ministry of Agriculture and Rural Development; Federal Ministry of Interior; Office of the National Security Adviser; Directorate of State Services National Intelligence Agency; Nigeria Immigration Agency; Nigeria Customs Service; Nigeria Security and Civil Defence Corps; Federal Fire Service; National Agency for Food and Drug Administration and Control; National Emergency Management Agency; National Universities Commission; National Biosafety Management Agency; National Biotechnology Development Agency; National Orientation Agency; National Research Institute for Chemical Technology; University of Abuja; Sheda Science and Technology complex; Manufacturers Association of Nigeria; Nigerian Association of Chambers of Commerce, Industry, Mines & Agriculture; Standard Organization of Nigeria; Nigeria Police Force; Institute of Chartered Chemist of Nigeria; and Chemical Society of Nigeria.

The NAC&BWC is responsible, inter alia, for:

- Coordinating and overseeing the implementation of the CWC and BWC;
- Serving as the National Focal Point for effective coordination of the activities of the relevant ministerial departments and agencies in the implementation of the CWC and BWC;

- Acting as liaison with the OPCW and BWC Implementation Support Unit; and

- Sensitizing the relevant stakeholders involved in the implementation of the CWC and BWC through meetings and workshops.

Source: BWC/MSP/2007/WP.8, dated 13 December 2007, "Nigerian Experience of the Biological and Toxin Weapons Convention", submitted by Nigeria; and page dedicated to the National Authority on Chemical and Biological Weapons Conventions (NAC&BWC) on the website of the Office of the Secretary to the Government of the Federation (https://www.osgf.gov.ng/offices/political-affairs/nat-authority-chemical-biological-weapon-convention)

▼ Group discussion of participants of the first Biosecurity Diplomacy workshop for young scientists from the Global South, held in 2019 in Vevey, Switzerland. Photo credit: BWC ISU.

Box 23 – Focus on South Africa's experience

"6. The Act (Act no 87 of 1993) prescribes the establishment of a statutory body, the South African Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) which is appointed by the Minister of Trade and Industry. The NPC is responsible for all aspects related to the implementation of all conventions, treaties and other international agreements pertaining to the non-proliferation of weapons of mass destruction. The NPC is also the nodal point for communication with the ISU.

7. The NPC utilises technical committees to provide it with technical advice on relevant issues. The committee on BTWC consists of representatives from all the relevant government departments (Health, Agriculture, International Relations and Cooperation, Defence); industry and civil society. This committee provides input on policy matters, legislation and the preparation of national positions. It also plays a role in the gathering of information and preparation of the annual CBM declarations.

8. The NPC is supported by a Secretariat (NPS), which provides administrative and other support functions for the NPC, which includes the management of all registrations, applications for import and export permits, provision of technical support to South African delegations to all meetings and conferences and provision of secretarial and other administrative support to the committees of the Council. The section of the NPS responsible for the BTWC and the CWC consists of 2 individuals."

Source: BWC/MSP/2013/MX/WP.10, dated 7 August 2013, "Implementation of the BTWC in South Africa", submitted by South Africa

Alternatively, States Parties may opt for a decentralised structure, whereby several entities have specific responsibilities for BWC implementation. If a State Party opts for a decentralised structure, it should ensure inter-ministerial coordination amongst all relevant governmental entities which have been assigned roles with regard to the BWC and consider designating focal points within each such entity in order to facilitate consultations and the collection of relevant data.

Governmental entities that may have responsibility for issues relevant to the BWC include:

- Authorities responsible for regulating and licensing laboratories, research institutions, or other facilities holding BWC relevant biological agents, toxins, means of delivery and equipment;
- Authorities responsible for regulating and licensing the transfer (import, export, transit, etc.) of BWC relevant biological agents, toxins, means of delivery, equipment and technologies;
- Enforcement authorities;
- Border control authorities;
- Emergency management authorities; and more generally
- Relevant government departments including the Office of the Prime Minister or Head of Government, the Office of the Attorney-General, the Ministries of Agriculture, the Environment, Foreign Affairs, Defence, Health, Education, Science and Technology, Industry, Interior, Justice, Trade, Transportation, International Development and Co-operation.

Box 24 – Focus on the United Kingdom's experience

"1. On 30 July 2018, the UK published an overarching national biological security strategy. This brings together, and sets out in one place for the first time, the wide range of activity carried out across government departments and agencies to protect UK citizens and British interests from the risk of a significant infectious disease outbreak, no matter the source – natural, deliberate or accidental. The strategy also explains how in the future the UK will coordinate its activity more strongly and take a truly comprehensive approach to meet the evolving risks (and opportunities) in this area. This will mean closer work between government departments, so that prevention activity, the deployment of response capabilities, research programmes, and our engagement with international partners, industry and academia align and their impact is maximised. [...]

6. Governance for much of the activity described in the UK's new strategy falls within government departments' existing portfolios and governance mechanisms. However, the strategy outlines commitments that will only be met if the Government works together across the diverse range of departments

and agencies involved. A senior cross-Government governance board will be responsible for these commitments (as well as any new areas of work or identified gaps that emerge through implementation of the strategy). This governance board will report to the National Security Council through the Home Office Security Minister. The Government Chief Scientific Adviser will maintain an oversight of developments under the strategy."

Source: BWC/MSP/2018/MX.3/WP.4, dated 31 July 2018, "Strengthening national implementation: The UK Biological Security Strategy 2018", submitted by the United Kingdom of Great Britain and Northern Ireland. The biological security strategy is accessible at https://www.gov.uk/government/publications/biological-security-strategy

Regardless of which approach is chosen, it is important that States Parties, when designating or establishing the authorities to be assigned responsibilities in relation to BWC implementation, clearly assign functions, responsibilities and powers, and allocate the necessary human, technical, and financial resources to enable them to discharge their respective mandates. In particular, States Parties may wish to pay particular attention to certain functions.

Responsibility should be assigned to one or several entities to:

- Act as a national point of contact for the ISU and other States Parties;
- Collate all necessary information and prepare annual submission of CBMs (see Box 3) to the ISU;
- Propose and support the adoption of legislative, regulatory and other measures to implement the BWC;
- Administer the licensing regimes established with respect to the non-prohibited activities involving biological agents or toxins, and related facilities;
- Supervise and monitor the enforcement of the implementing measures;
- Administer the control regime established for internal and international transfers of BWC-relevant biological agents, toxins, items and technologies and ensure legitimate activities with biological agents are not hampered;
- Establish and operate a national bioemergency preparedness and response system, and liaise with relevant authorities to respond and investigate accidental or deliberate release of high-consequence biological agents and toxins; and
- Conduct, promote, facilitate or encourage awareness-raising, education, outreach and training regarding the BWC, biosafety and biosecurity, national implementing measures for scientists and all other relevant professionals and individuals.

Box 25 – Additional resources for the development of the institutional framework

States Parties seeking assistance for the development of measures setting up the relevant institutional framework for the implementation of the BWC could find it useful to refer to the resources listed in Annex 3. In addition, Annex 4 provides further information on assistance programmes and initiatives.

Of specific relevance to this Module are:

- The Working Paper on National Authorities for BWC Implementation: Regional and Global Experiences (*La Autoridad Nacional para la Convención sobre Armas Biológicas: experiencias regionales y globales),* published by the United Nations Regional Centre for Peace, Disarmament and Development in Latin America and the Caribbean (UNLIREC). This paper is available in Spanish only at https://unlirec.org/wp-content/uploads/2018/04/AutoridadNacional_CAB.pdf.

- The Regulatory Guidelines developed by VERTIC for the implementation of the BWC which provide guidance on the establishment or designation of governmental bodies responsible for BWC implementation. They are available at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

MODULE III – ADOPTION OF PENAL MEASURES IN RELATION TO THE PROHIBITIONS SET FORTH IN THE BWC (MEASURES RELEVANT TO ARTICLES I, III AND IV)

Pursuant to Article IV of the BWC, each State Party must, *"in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere."*

Several Review Conferences have also called for appropriate measures by all States Parties to implement Article III,[30] under which States Parties have undertaken "not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of this Convention".

Considering the above and as part of the national implementing measures to be taken, States Parties should adopt penal measures to establish the violations of the prohibitions identified in the BWC as criminal offences as well as related penalties in their national law. They should also adopt the necessary procedural penal measures to enable investigation and prosecution of prohibited acts.

30 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article III, paragraph 9; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article III, paragraph 9; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article III, paragraph 8; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 2; and BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 1.

3.1 Scope of the national implementing measures

The penal measures to be taken by States Parties to implement the BWC could entail the following:

3.1.1 Establishing violations of the BWC prohibitions as offences

Scope of the prohibitions: definition of terms

Biological weapons

In establishing the offences, States Parties should be mindful that the BWC does not contain definitions of terms. Except in its Preamble, the term "biological weapons" is not used in the BWC; nor does the BWC provide an explicit definition of this term or specify the substances or items which, based on their specific properties, could be considered as constituting a biological weapon. Instead, Article I prohibits the conduct of certain activities involving:

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

Thus, the essential criterion at the core of the prohibitions established in the first paragraph of Article I is the *purpose* for which the microbial or other biological agents or toxins are developed, produced, stockpiled or otherwise acquired or retained, not their properties. This is commonly referred to as the "general purpose criterion" (GPC).

The GPC acknowledges the dual-use nature of the biological agents and toxins and also enables the BWC to avoid hampering the economical and technological developments of States Parties in the field of peaceful biological activities. It also enables the BWC to remain relevant irrespective of developments in science and technology, and to cover any as-yet-unknown agents and toxins that might be used as weapons in the future.

Article I does not therefore either define or list those weapons, equipment or means of delivery which constitute "biological weapons". Instead, the prohibitions in paragraph 2 of Article I extend to any weapon, equipment of means of delivery which has been *designed to use biological agents or toxins for hostile purposes or in armed conflict*.

Biological agents and toxins

Similarly, the BWC defines neither the "biological agents" nor the "toxins" to which it refers. Through the Review Conferences, however, States Parties have affirmed that the BWC is comprehensive in its scope and that Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the BWC, in the fields of microbiology, genetic engineering, biotechnology, molecular biology and any applications resulting from genome studies, where intended to be used for purposes inconsistent with the objectives and the provisions of the BWC.[31]

Successive Review Conference have also deemed it necessary to clarify that all naturally or artificially created or altered microbial or other biological agents, or toxins, as well as their components, including toxins (both proteinaceous and non-proteinaceous) of a microbial, animal or vegetable nature and their synthetically produced analogues, regardless of their origin and method of production and whether they affect humans, animals or plants, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, are also covered under the BWC.[32]

In incorporating the Article I prohibitions into their national legislation, States Parties should therefore ensure that the scope of the prohibitions is not changed as a result of the introduction of definitions or use of terms which would not be consistent with the BWC. Thus, if a State Party determines that it is necessary to introduce definitions of the terms used in the BWC into its legislation, it should ensure that the meaning or scope of such terms remain in line with the BWC.

31 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article I, paragraph 1; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article I, paragraph 1; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article I, paragraph 1; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article I, paragraphs 2 and 5; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article I, paragraphs 2 and 3; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article I, paragraph 5.

32 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article I, paragraphs 1 and 2; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article I, paragraphs 1 and 2; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article I, paragraphs 1 and 2; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article I, paragraphs 2, 5 and 6; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article I, paragraphs 2 and 3; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article I, paragraphs 4 and 5.

Transfer

Equally, the term "transfer" is not further defined in the Convention. The prohibition set forth in Article III covers any direct or indirect transfer, to any recipient whatsoever at the international, national or sub-national levels.[33] Thus, this prohibition covers both international transfers and internal movements, which may include export, import, transit, transhipment, as well as any brokering activities. The prohibition also covers any type of transfers, including intangible transfers.

Scope of the prohibitions: the prohibited activities

The measures taken domestically to translate the prohibitions set forth in the BWC should reflect the scope of the prohibitions established in Articles I and III, including as reflected in the understandings reached at Review Conferences. In that regard, several Review Conferences have affirmed that the use, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I.[34]

The penal measures under the BWC should, therefore, prohibit and establish offences with respect to the following acts:

- To develop, produce, stockpile, or otherwise acquire, retain or use in any way and under any circumstances, the biological agents, toxins, weapons, equipment and means of delivery specified in Article I;
- To transfer to any recipient whatsoever, directly or indirectly, such agents, toxins, weapons, equipment and means of delivery; and
- To assist, encourage, induce in any way to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment and means of delivery specified in Article I.

33 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article III, paragraph 8; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article III, paragraph 8; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article III, paragraph 8; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 1; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 1; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article III, paragraph 1.

34 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article I, paragraph 3; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article I, paragraph 3; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article I, paragraph 3; and BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article I, paragraph 3.

In taking the penal measures, States Parties should also be mindful of their obligations under other international instruments, to seek synergies and optimise implementation efforts. For example, the second operative paragraph of Security Council resolution 1540 (2004) requires all UN Member States to adopt and enforce appropriate effective laws to prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use biological weapons and their means of delivery, in particular for terrorist purposes, as well as attempts to engage in any of the foregoing activities, participate in them as an accomplice, assist or finance them.

States Parties could, therefore, consider broadening the scope of the prohibitions to be established at national level for BWC implementation by adding the following acts:

- To transport the biological agents, toxins, weapons, equipment and means of delivery specified in Article I;
- To assist, encourage, induce, finance, participate as an accomplice or otherwise aid or attempt to commit any of the prohibited acts specified in Article I.

In addition to the fulfilment of one of the obligations under Security Council resolution 1540 (2004), introducing these additional prohibitions into the scope of the BWC implementing measures might also be valuable as a contribution to the State Party's efforts to prevent the commission of one of the BWC prohibited activities.

Box 26 – The results of VERTIC's biological weapons legislation surveys

In November 2016, VERTIC published an analysis of the surveys it had conducted on the BWC implementing legislation adopted by 131 States Parties, six Signatory States and nine States which were then neither Party nor Signatory to the BWC. A total of 95 distinct criteria relating to specific sets of measures were used, including offences and penalties for prohibited activities involving biological weapons and biological agents and toxins. In its report, VERTIC noted the following, which illustrates the possible approaches in incorporating the prohibitions into national legislation:

"Those offences concerning activities directly involving biological weapons (development, production, stockpiling, acquisition, retention, transfer, transport or use) were located in laws intended primarily to give effect to the BWC, such as amendments to the Penal Code (in civil law States) or the adoption of a BWC Act (in common law States). Some States included such measures in hybrid laws relating to the prohibition of both biological and chemical weapons. This approach was taken by States which had not previously given effect to the BWC upon adherence many years earlier, or which wished to update their existing BW-related provisions, or indeed which had only recently adhered to the BWC, and then adhered to the Chemical Weapons Convention and sought to fulfil both BWC and CWC legislative requirements through a harmonized approach. A group of States with a similar legal tradition have taken the approach of prohibiting these biological weapons activities in legislation relating to arms, ammunition and explosive weapons. Even fewer States employed a hybrid approach of establishing these biological weapons offences alongside those for chemical, (radiological) and nuclear weapons in 'weapons of mass destruction (WMD) Acts', or in legislation concerning terrorism prevention. Offences for breaches of transfer controls were located in laws concerning dual-use strategic goods and counter-terrorism."

Source: VERTIC, Biological Weapons Convention, Report on National Implementing Legislation, *National Implementation Measures Programme*, November 2016

▼ BWC Universalisation Workshop for IGAD (Inter-Governmental Authority on Development) Member States in Djibouti City in 2018. Photo credit: BWC ISU

3.1.2 Establishing the related penalties

The penalties for the offences established should be, while proportional to the seriousness of the offence, severe enough to serve as a deterrent. The penalty level could also change in view of aggravating factors as necessary, such as whether or not an activity caused death to one or more persons or whether the prohibited act was committed for the development of a WMD programme, or in relation to terrorist acts. Some laws include or focus more heavily on prohibitions relating to the violation of licensing and regulated activities, introducing penalties for failure to comply with licensing procedures. Offences also take the form of failing to notify authorities or police of prohibited or suspicious activities.

3.1.3 Establishing appropriate jurisdiction

Several Review Conferences have called upon States Parties to adopt, in accordance with their constitutional processes, measures, including penal legislation, designed to apply within their territory, or to areas under their jurisdiction or control anywhere. Such mesures should also apply, if constitutionally possible and in conformity with international law, to actions taken anywhere by natural or legal persons possessing their nationality.[35]

In line with the above, States Parties should, therefore, consider establishing jurisdiction over any prohibited act whether committed:

- Within their respective territory or in any other place under their jurisdiction or control, as recognised by international law, by any natural or legal persons, irrespective of their nationality (territorial jurisdiction);
- Outside their territorial jurisdiction by any natural or legal persons possessing their nationality (personal jurisdiction).

35 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 11(b); BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 11(b); BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraph 11(ii).

Box 27 – Focus on the United Kingdom's implementing measures

Excerpts from the Biological Weapons Act 1974, as amended:

"Extraterritorial application of section 1

1A (1) Section 1 applies to acts done outside the United Kingdom, but only if they are done by a United Kingdom person.

(2) Proceedings for an offence committed under section 1 outside the United Kingdom may be taken, and the offence may for incidental purposes be treated as having been committed, in any place in the United Kingdom.

(3) Her Majesty may by Order in Council extend the application of section 1, so far as it applies to acts done outside the United Kingdom, to bodies incorporated under the law of any of the Channel Islands, the Isle of Man or any colony.

(4) In this section "United Kingdom person" means a United Kingdom national, a Scottish partnership or a body incorporated under the law of a part of the United Kingdom.

(5) For this purpose a United Kingdom national is an individual who is

(a) a British citizen, a British Dependent Territories citizen, a British National (Overseas) or a British Overseas citizen;

(b) a person who under the British Nationality Act 1981 (c. 61) is a British subject; or

(c) a British protected person within the meaning of that Act.

(6) Nothing in this section affects any criminal liability arising otherwise than under this section."

3.2 Complementary measures to enable enforcement

3.2.1 Granting investigation, enforcement and prosecution powers to relevant authorities

To enable the enforcement of the penal measures enacted, and ensure that the relevant authorities are empowered to prevent, interrupt, prosecute, and punish the commission of prohibited acts, States Parties should ensure that the relevant authorities have been granted appropriate enforcement powers to, for example:

- Search and inspect premises; and
- Seize or forfeit biological agents, toxins, weapons, equipment and means of delivery involved in the commission or attempt of commission of the prohibited acts.

Box 28 – Focus on Niue's implementing measures

Excerpts from the Biological Weapons Convention Act 2018:

"**8 Designation of inspectors**

The Minister may designate a suitable person or class of persons as an inspector for the purpose of the enforcement of this Act, and set conditions applicable to the person's inspection activities.

[…]

9 Entry and inspection

(1) For the purpose of ensuring compliance with this Act, an inspector may enter and inspect, at any reasonable time, any place in which the inspector believes on reasonable grounds there is -

(a) any microbial or other biological agent or any toxin; or
(b) any weapon, equipment, or means of delivery designed to use such an agent or toxin; or
(c) any information relevant to the administration of this Act.

(2) An inspector carrying out an inspection may do any of the following:

(a) require the attendance of, and question, any person who the inspector considers will be able to assist in the inspection;

(b) examine, take samples of, detain, or remove any thing referred to in subsection (1);

(c) require any person to produce for inspection, or to copy, any document that the inspector believes contains any information relevant to the administration of this Act;

(d) require that any individual in charge of the place take any measures that the inspector considers appropriate;

(e) use or cause to be used any computer or data processing system to examine any data contained in or available to the computer system;

(f) reproduce or cause to be reproduced any record from the date, in the form of a printout or other intelligible output, and remove the printout or other output for examination or copying;

(g) use or cause to be used any equipment at the place to make copies of any data or any record, book of account, or other document.

[…]

10 Warrant to enter dwelling-house

[…]

11 Search and seizure

[…]"

▲ Participants from Sri Lanka discuss the establishment of a national inventory of dangerous pathogens with experts from the Dutch Biosecurity Office. Photo credit: BWC ISU.

Box 29 – Focus on Saint Kitts and Nevis' implementing measures

Excerpts from the Biological Weapons Act 1991:

"7. If a magistrate is satisfied by evidence on oath that there are reasonable grounds for suspecting that an offence under section 3 has been or is about to be committed he may grant a search warrant authorising a member of the Police Force not below the rank of sergeant, named therein -

(a) to enter at any time within three months of the date of the warrant, any premises or place named therein, if necessary by force, and search such premises or place and every person found therein;

(b) to inspect any document found in the premises or place or in the possession of any person found therein and to take copies of, or seize and detain any such document;

(c) to inspect, seize and detain any equipment so found; and

(d) to inspect, sample, seize and detain any substance so found"

Developing law enforcement, including intelligence and forensic capacities and capabilities to identify, detect, investigate and prosecute commission of, or attempts to commit, a prohibited act is also key to ensure proper enforcement of the BWC implementing measures.[36] In support of the law enforcement authorities, having designated laboratories for sampling and analysis, and the conduct of microbial forensics, may also need to be considered.

3.2.2 Measures to ensure the safe handling of seized or forfeited materials or items

Pursuant to Article II, States Parties must take all necessary safety precautions to protect populations and the environment when carrying out the destruction and/or diversion of the biological agents, toxins, weapons, equipment and means of delivery specified in Article I. States Parties having undertaken such destruction or diversion should also provide appropriate information to all States Parties via the Confidence-Building Measures (CBM Form F).

36 Australia reported on its experience in that area at the 2007 Meeting of Experts in BWC/MSP/2007/MX/WP.12, "Increasing the Technical Expertise of Law Enforcement Agencies to Assist Counter-Proliferation Initiatives".

Procedures should, therefore, be specified to ensure that:

- Seized or forfeited biological agents, toxins, weapons, equipment or means of delivery are appropriately handled until their safe destruction or diversion in accordance with relevant biosafety and biosecurity measures (see Module V); and
- Appropriate records are maintained, including to ensure appropriate reporting as part of the annual CBM submissions.[37]

3.2.3 Measures to ensure coordination among relevant national authorities, and to permit international cooperation and mutual legal assistance

The establishment of procedures to ensure timely and appropriate coordination between all relevant authorities, in particular the law enforcement authorities and public health authorities, may also be critical in the prevention and prosecution of prohibited acts.[38]

The commission of a prohibited act could involve transnational elements, with perpetrators or participants in the commission of the prohibited act being located in various countries. There may therefore be a need for international cooperation and mutual legal assistance in the investigation and prosecution of suspected offences (e.g. to facilitate the exchange of information and collection of evidence) and in the subsequent judicial proceedings (e.g. to provide grounds for the transfer of penal proceedings, the recognition of foreign penal judgements or extradition).

States Parties could, therefore, consider establishing a legal framework for such cooperation and mutual legal assistance between States Parties with respect to the offences related to the BWC. Such a framework may already be in place in furtherance of other international instruments, such as Security Council resolution 1540 (2004), the organised crime or anti-terrorism conventions.[39]

37 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article II, paragraph 6; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article II, paragraph 6; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article II, paragraph 6.

38 Illustrations of the need for clear lines of communication among public health and law enforcement authorities in the case of a deliberate or accidental release of a biological agent can be found in BWC/MSP/2007/MX/WP.11, dated 15 August 2007, "Effective Enforcement of National Legislation", submitted by the United States of America".

39 As reported by UNODC in its publication *The International Legal Framework against Chemical, Biological, Radiological and Nuclear (CBRN) Terrorism*: "All the international legal instruments

Box 30 – Additional resources for the development of penal measures

States Parties seeking assistance for the development of relevant penal measures may refer to Annex 3 which lists resource materials which States may find useful to consult, including model provisions as developed by VERTIC and regional organisations, as well as legislation databases linking to actual legislative or regulatory texts adopted by States Parties for the implementation of the BWC. Annex 4 further provides information on assistance programmes and initiatives. Of specific relevance to this Module are:

- VERTIC: Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 (2004)[40]; and
- ICRC and VERTIC: Model Law – The Biological and Toxin Weapons Crimes Act, both available from the VERTIC website at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

States Parties could also find it useful to refer to the publication *The International Legal Framework against Chemical, Biological, Radiological and Nuclear (CBRN) Terrorism*, developed by the United Nations Office on Drugs and Crime (UNODC) as one of the modules of the Counter-Terrorism Legal Training Curriculum. This publication, dedicated to the offences related to CBRN terrorism, was tailored for use in capacity-building initiatives addressing more particularly policymakers, legislators, judges and prosecutors. It is available at https://www.unodc.org/documents/terrorism/for%20web%20stories/1-WS%20CBRN%206%20modules/CBRN_module_-_E.pdf.

Building upon this publication, UNODC also launched an e-Learning module on the international legal framework against CBRN terrorism, available at https://www.unodc.org/unodc/en/terrorism/latest-news/2019_e-learning-cbrn.html

against CBRN terrorism include an obligation to extradite or prosecute, also known by the Latin term *aut dedere aut judicare*. The relevant provisions state that, whenever the extradition of an individual present in a State's territory is requested, that State must either hand over the person concerned to the requesting State or submit the case to the competent domestic authorities for the purpose of prosecution."

40 At the time of writing, this Sample Act was under revision.

4 MODULE IV – ESTABLISHING AN EFFECTIVE NATIONAL CONTROL REGIME FOR TRANSFERS (MEASURES RELEVANT TO ARTICLES III AND X)

Under Article III, BWC States Parties undertake *"not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I".*

Consecutive Review Conferences have called for appropriate measures, including effective national export controls, by all States Parties, to implement this Article, in order to ensure that direct and indirect transfers relevant to the Convention, to any recipient whatsoever at the international, national or sub-national levels, are authorised only when the intended use is for purposes not prohibited under the Convention.[41] The Fourth Review Conference in 1996 also noted that States Parties should consider ways and means to ensure that individuals or subnational groups are effectively prevented from acquiring, through transfers, biological agents and toxins for other than peaceful purposes.[42]

In establishing any such measures, States Parties should be careful not to impose restrictions and/or limitations on transfers which may hamper the economic or technological development of States Parties or international cooperation in the field of peaceful biological activities under Article X.[43]

41 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article III, paragraphs 8 and 9; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article III, paragraphs 8 and 9; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article III, paragraph 8. See also: BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 1; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 1; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article III, paragraph 1.

42 See BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 3.

43 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II,

In order to ensure the necessary balance between the obligations stemming from Article III and other articles of the Convention, in particular Article X as well as Article VII, the relevance of the control measures taken should be regularly reviewed in order to maintain consistency with the objectives and provisions of all articles of the BWC.

There is no uniform approach to the implementation of Article III, and it is up to each State Party to determine based on its own specificities how to implement it. Some States Parties may, for example, decide to adopt implementing measures as part of their specific BWC implementing act or WMD or CBRN act. Others may build upon existing control regimes established to regulate the transfer of other dual-use or strategic goods, and incorporate relevant implementing measures into an export control act or strategic goods act.

4.1 Scope of the national implementing measures

The measures to be taken by States Parties to control transfers relevant to the BWC could entail the following:

4.1.1 Defining the scope of the control regime

As discussed in Module IV, certain transfers are completely prohibited by the BWC. The implementing measures governing the transfers relevant to the BWC should clearly establish that transfers shall be authorised only when the intended use is for purposes not prohibited,[44] and when conducted in accordance with the control regime provisions.

Such a control regime could relate to both international (cross-border) transfers as well as to internal (within the country) transfers.

As transfers may refer to various types of activities, States Parties should consider specifying the activities intended to be controlled, also taking into account their obligations under other international instruments, including

Article III, paragraph 10; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article III, paragraph 10; BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article III, paragraph 10; BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 4; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 2; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article III, paragraph 2.

44 See BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 2; and BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article III, paragraph 1.

Security Council resolution 1540 (2004). Relevant activities may include: the import, export, transit, and trans-shipment; as well as activities such as the brokering, trading in, negotiating, or selling.

In view of Security Council resolution 2035 (2016), which encouraged UN Member States to control access to intangible transfers of technology and to information that could be used for weapons of mass destruction and their means of delivery, States Parties could also consider regulating the intangible transfer of technologies.[45]

Box 31 – Focus on European Union legislation

Excerpts from Council Regulation (EC) No. 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items:[46]

"Article 1

This Regulation sets up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Article 2

For the purposes of this Regulation: [...]

2. 'export' shall mean:

(i) an export procedure within the meaning of Article 161 of Regulation (EEC) No 2913/92 (the Community Customs Code);

45 The United Kingdom reported on its experience in establishing controls over intangible technologies at the 2003 and 2007 Meetings of Experts through:

- BWC/MSP.2003/MX/WP.65, dated 1 September 2003, "United Kingdom – Legislation Governing Intangible Technology";
- BWC/MSP/2007/MX/WP.2, dated 7 August 2007, "Two Issues in BTWC National Implementation: The Challenge of Intangible Technology Controls and Export Licensing Enforcement".

The Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003, referred to in these working papers, was subsequently repealed and replaced by the Export Control Order 2008.

46 The full text of the Regulation is available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R0428-20191231&from=EN. Pursuant to its Article 24, each EU Member State must take appropriate measures to ensure proper enforcement of all the provisions of this Regulation. Summary information on the EU export control regime over dual-use items is available at https://policy.trade.ec.europa.eu/help-exporters-and-importers/exporting-dual-use-items_en.

(ii) a re-export within the meaning of Article 182 of that Code but not including items in transit; and

(iii) transmission of software or technology by electronic media, including by fax, telephone, electronic mail or any other electronic means to a destination outside the European Community; it includes making available in an electronic form such software and technology to legal and natural persons and partnerships outside the Community. Export also applies to oral transmission of technology when the technology is described over the telephone;

[...]

5. 'brokering services' shall mean:

— the negotiation or arrangement of transactions for the purchase, sale or supply of dual-use items from a third country to any other third country, or

— the selling or buying of dual-use items that are located in third countries for their transfer to another third country.

For the purposes of this Regulation the sole provision of ancillary services is excluded from this definition. Ancillary services are transportation, financial services, insurance or re-insurance, or general advertising or promotion;

[...]

7. 'transit' shall mean a transport of non-Community dual-use items entering and passing through the customs territory of the Community with a destination outside the Community"

4.1.2 Establishing control lists

National control lists should be established to identify the biological agents, toxins, items and technologies subject to control. However, as mentioned above in Module IV, it will be important to ensure that such lists do not change the scope of the prohibitions to be set forth. Such lists should be focused on the biological agents, toxins, weapons, equipment, means of delivery, and technologies which, although they may have peaceful applications or may not have been designed to be used as biological weapons, are needed and could serve to develop, produce, stockpile or could be used as biological weapons.

Once established, the control lists should be regularly reviewed and updated as necessary, taking into account scientific and technological developments.

States Parties may wish to develop their own national lists, or alternatively to refer to internationally or regionally established control lists. If the choice is made to develop country-specific national lists, such lists should preferably be part of the regulatory measures to be enacted in furtherance of the legislative measures establishing the control regime. This will facilitate the future revision of the lists to incorporate any amendments which may be required to be made at regular intervals to reflect developments in science and technology.

The adoption of control lists could also facilitate a State Party's compliance with its obligations under Security Council resolution 1540 (2004), which recognises in its operative paragraph 6 the utility of such lists in implementing the resolution.

Box 32 – International and regional control lists

Relying on and referring to existing international or regional control lists may present the advantage of avoiding having to use resources for the development of national lists. They also enable a global or regional harmonisation of the biological agents, toxins, items and technologies subject to control, which may facilitate trade operations. Such lists have been developed by:

- The Australia Group, which has developed: a list of dual-use biological equipment and related technology and software; a list of human and animal pathogens and toxins; and a list of plant pathogens. The lists are available in various languages on the Australia Group website at https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/controllists.html

- The Participating States of the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies, which have developed the Munitions List and the List of Dual-Use Goods and Technologies. More information can be found on the Wassenaar Arrangement website at https://www.wassenaar.org

- The Missile Technology Control Regime (MTCR) Partners, which have developed Guidelines for the control of missiles for the delivery of all types of weapons of mass destruction (WMD), including biological weapons. An Annex to the Guidelines lists equipment, software and technology, both military and dual-use, that are relevant to missile development, production, and operation. More information can be found on the MCTR website at https://mtcr.info

- The European Union: a list of dual-use items can be found in Annex I to Council Regulation (EC) No. 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R0428-20191231&from=EN The European Union has also adopted a Common Military List which includes: Chemical agents, "biological agents", "riot control agents", radioactive materials, related equipment, components and materials. This list is regularly updated and specifies the items covered by Council Common Position 2008/944/CFSP defining common rules governing control of exports of military technology and equipment. The list in its version as adopted on 17 February 2020 is available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XG0313(07)

- The UN Regional Centre for Peace, Disarmament and Development in Latin America and the Caribbean (UNLIREC) developed a *Guide to Control Lists* to provide Caribbean States with a ready-made control list solution that can be adopted or adapted by States seeking to implement their obligations vis-à-vis Security Council resolution 1540 (2004), including with regard to the BWC. The *Guide* provides step-by-step information on how to formulate a control list, and proposes a control list construct (the Caribbean Control List (CCL)). The Guide also contains a Caribbean WMD Focus List to facilitate the practical implementation of the CCL within a national context. While focused on the Caribbean context, the methodologies used in the *Guide to Control Lists* can be applied by any State. The Guide is available both in English and Spanish. The *Guide to Control Lists* is made available upon request by UNLIREC (info@unlirec.org)

4.1.3 Establishing a national licensing regime

Each State Party is free to determine the best way to control transfers of BWC-relevant biological agents, toxins, items and technologies. One such way consists in subjecting the export of such agents, toxins, items and technologies listed on the control lists to licensing or authorisation. Extending such licensing requirements to other related activities, such as import, re-export, transit, trans-shipment, brokering, trading in, negotiating, or selling, or requiring prior notification thereof could also be considered as a means to "ensure that individuals or subnational groups are effectively prevented from acquiring, through transfers, biological agents and toxins for other than peaceful purposes."[47]

The relevant national implementing measures could, thus:

- Provide for the requirement to obtain a licence to conduct a certain type of operations (export, import, etc.) involving specific biological agents, toxins, items or technologies contained in the control lists.
- Establish the conditions for a license, as well as provide the appropriate legal basis for the relevant authority to specify the application procedure, including associated fees if any. As part of the conditions for a licence, States Parties could consider requiring the provision of a certificate which would indicate the name and location of the end-user, and the intended end-use of the agents, toxins, items or technologies for which a licence is requested. States Parties may also consider requiring registration of exporters, as well as, where applicable, other persons involved in transfer operations.
- Provide for the conditions of a license. If the system provides for a general license, valid for several operations of the same type over a certain period of time, for monitoring purposes, the national measures could provide for a reporting process requiring licensees to notify or report to the competent national authority details on the specific operations (including destinations, end-users and quantities involved).
- Establish licensing exemptions. In furtherance of Article VII and Article X, States Parties could consider exempting the transfer of BWC-relevant biological agents, toxins, items or technologies (such as e.g.: biological agent, pathogen, animal, and human clinical samples; vaccines; and immunotoxins) from the licensing requirements, where required for emergency or humanitarian assistance.

47 See BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article III, paragraph 3.

- Designate or establish the licensing authority and grant such authority any necessary powers for the discharge of its mandate, including to seek information from the licence applicant, as well as appropriate other control functions.
- Establish procedures for appealing decisions denying licence applications.
- Establish offences, and administrative, penal and/or civil penalties for engagement in a transfer of listed biological agents, toxins, weapons, equipment, means of delivery or technology without license, or in contravention with the prohibitions, license requirements or conditions attached thereto.

Box 33 – Focus on Norway's experience

"179. Norway has established guidelines to limit the risks of proliferation and terrorism involving biological weapons by controlling tangible and intangible transfers that could contribute to BW activities by states or non-state actors, consistent with Article III of the Biological Weapons Convention. In accordance with Article X of the Biological Weapons Convention, these Guidelines are not intended to impede biological trade or international cooperation for peaceful purposes. The guidelines form the basis for controlling transfers of materials, equipment, technology and software that could contribute to BW activities to any destination beyond the Government's national jurisdiction or control.

180. Norway sees export licensing as a vital means of ensuring that the legitimate trade in biological agents and related equipment can proceed unfettered. Careful regulation of potentially sensitive exports helps to reduce the risk that companies will unwittingly export products for use in BW programmes, thereby incurring severe penalties. This gives companies greater confidence to trade in products that have the potential to be used in the production of BW. Licensing measures have a minimal impact on the total trade in biological agents and dual-use items and equipment. Export licences deter proliferation by increasing the visibility of trade in relevant materials, and provide authority to stop a sale if the product concerned is likely to contribute to a BW programme. The licensing measures only affect sales to a small number of countries where there is evidence of an interest in developing or maintaining a BW capacity or of a risk of diversion to terrorists groups. The activities are limited to non-proliferation measures, and are not intended to hinder legitimate economic development in other countries."

Source: BWC/CONF.VIII/INF.4, dated 10 October 2016, "Implementation of Article X of the Convention, Background information document submitted by the Implementation Support Unit"

4.1.4 A catch-all clause

The national implementing measures to implement Article III could also provide for a catch-all clause. Such a clause enables the competent authorities to require a licence for, or impose other type of control measure on, the transfer of any material, item or technology which is not on the control lists, but the transfer of which is suspected to contribute to the development or production of biological weapons, in violation of the BWC-related prohibitions.

Having in place a system to oversee research and development in the life sciences may assist in that regard by alerting authorities of potential new risks and threats, and potential new dual use substances, items and technologies.

4.1.5 Adopting physical protection measures

The national implementing measures should provide for physical protection measures to protect and safeguard the biological agents and toxins, as well as BWC-relevant items when stored at borders or during transportation,[48] including through measures to control access to and handling of such materials and items (see also Module V).

4.1.6 Providing for appropriate coordination procedures

Procedures should also be established to ensure appropriate information sharing and coordination amongst relevant authorities to address cases of suspicious prohibited activities. This may be of relevance: at borders where several authorities may be involved (customs, border police, port authorities, etc.); in States with a decentralised structure such as federal States; or when there are several regulatory authorities exercising control over the same materials, items or technologies.

4.2 Complementary measures

As part of any possible complementary measures to further the implementation of Article III, States Parties could consider the following:

48 In BWC/MSP/2018/MX.3/WP.1/Rev.1, dated 10 August 2018, "The transport of biological agents must be protected by biosecurity measures", Chile, Colombia, Panama and Spain identified four different types of activities involving the transport of pathogens within the national territory, i.e.: the transport of imported biological material from the country's entry point to the facility where this material will be delivered; the transport between two facilities working with pathogens, both transfers of samples and/or pathogens; the transport of samples taken at particular locations, as a result of an epidemiological surveillance process, to the facility where the samples would be analysed or stored; and the transport from any point in the country to the final carrier that will transfer (export) the pathogen outside the national territory.

- Adopting guidelines and establishing awareness-raising and training programmes to assist relevant authorities, including front-line officers, to enable them to conduct effective controls.
- Conducting regular outreach to all relevant stakeholders, in particular life science researchers and research managers, the biotechnology industry and academia, concerning the requirements stemming from the national legislative and regulatory measures adopted in furtherance of Article III, to ensure awareness and compliance.
- Developing mechanisms for the oversight of scientific and technological developments. As part of such oversight mechanisms, States Parties could rely on the expertise of the industry associations and scientists to oversee the technological and scientific developments in the area, and to inform policy decisions regarding the biological agents, toxins, items and technologies of relevance to the BWC.

4.3 Synergies with other international instruments and initiatives

4.3.1 Security Council resolution 1540 (2004)

In accordance with Security Council resolution 1540 (2004), UN Member States must establish, develop, review, and maintain appropriate effective national export and trans-shipment controls over BW-related items, including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such exports and trans-shipments such as financing, and transporting that would contribute to proliferation, as well as establishing end-user controls.[49] Given the significant

49 Pursuant to operative paragraph 3 of resolution 1540, "all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of [...] biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:

(a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;

(b) Develop and maintain appropriate effective physical protection measures;

(c) Develop and maintain appropriate effective border controls and law enforcement efforts to detect, deter, prevent and combat, including through international cooperation when necessary, the illicit trafficking and brokering in such items in accordance with their national legal authorities and legislation and consistent with international law;

(d) Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over such items, including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such export and trans-shipment such as financing, and transporting that would contribute to proliferation, as well as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations".

overlap of these obligations with the measures necessary to implement Article III, States Parties should combine efforts and take measures implementing their international obligations under both instruments.

4.3.2 Other international arms control, disarmament and non-proliferation instruments

In initiating the process to implement Article III, States Parties should also consider whether any synergies could be established with regimes that may already be in place, or in the process of being developed, for the implementation of other international arms control, disarmament and non-proliferation instruments, such as the Chemical Weapons Convention. The measures to be established under these instruments may present many similarities with the control regime over the BWC-relevant biological agents, toxins, items and technologies.

4.3.3 Other instruments

Other instruments may also be of relevance such as:

- The Convention on Biological Diversity and the Cartagena Protocol on Biosafety. Although these are primarily concerned with genetically modified organisms, their requirements do contribute to ensuring the safe handling and use of such organisms – and reduction of any risks to human health. The Cartagena Protocol aims to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. The Protocol thus requires that an advanced informed agreement procedure be followed, prior to the first intentional transboundary movement of modified organisms for intentional introduction into the environment. The text of the Protocol is available at: https://bch.cbd.int/protocol/
- The International Standards for Phytosanitary Measures (ISPMs) adopted under the International Plant Protection Convention (IPPC), including the Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms (adopted in 1995, revised in 2005). The list of adopted standards is available at: https://www.ippc.int/en/core-activities/standards-setting/ispms/

Additional relevant instruments are listed in Box 53 in Module V.

Box 34 – Additional resources for the development of a transfer control regime

States Parties seeking assistance for the development of relevant implementing measures may refer to Annex 3 which lists resource materials which they may find useful to consult, including model provisions developed by VERTIC and regional organisations, as well as legislation databases linking to actual legislative or regulatory texts adopted by States Parties for BWC implementation. Annex 4 further provides information on assistance programmes and initiatives.

Of specific relevance to this Module is:

- *The Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 (2004)*[50], developed by VERTIC and available at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/
- The *Strategic Trade Control Enforcement Implementation Guide* developed by the World Customs Organization (WCO) and available at http://www.wcoomd.org/en/topics/enforcement-and-compliance/instruments-and-tools/guidelines/wco-strategic-trade-control-enforcement-implementation-guide.aspx
- The *Common Control List Handbook*, developed by the its not by the US but by the Australia Group and available at https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/documents/Australia-Group-Common-Control-List-Handbook-Volume-II.pdf

50 At the time of writing, this Sample Act was under revision.

5 MODULE V – BIOSAFETY AND BIOSECURITY MEASURES (MEASURES RELEVANT TO ARTICLE IV)

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

The Sixth, Seventh and Eighth Review Conferences further called upon States Parties to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures designed to ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorised access to and removal of such agents or toxins.[51] The Sixth Review Conference also called for appropriate measures by all States Parties to ensure that biological agents and toxins relevant to the Convention are protected and safeguarded, including through measures to control access to and handling of such agents and toxins.

At their annual meetings, States Parties had already recognised 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,[52] and ensuring that dangerous materials are not accessible to persons who might or could misuse them for purposes contrary to the Convention.[53]

Depending on the context in which the terms "biosafety" and "biosecurity" are used, these may have different meanings.[54] In 2008, States Parties noted their

51 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article IV, paragraph 11.c; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article IV, paragraph 11.c; and BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article IV, paragraph 11.

52 See BWC/MSP/2008/5, paragraph 21.

53 See BWC/MSP/2003/4, Report of the Meeting of States Parties, Volume I, Part II.

54 For example, the FAO defines "biosecurity" as a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and

common understanding, not to be construed as a definition or intended to be binding on States Parties, that, in the context of the Convention:

- *Biosafety* refers to principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and

- *Biosecurity* refers to the protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorised access to, retention or transfer of such material.[55]

In addition, the 2008 Meeting of States Parties also agreed on the value of national authorities defining and implementing biosafety and biosecurity concepts in accordance with relevant national laws, regulations and policies, consistent with the provisions of the BWC and taking advantage of relevant guidance and standards, such as those produced by the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (WOAH) and the World Health Organization (WHO). States Parties also agreed on the value of ensuring that such measures are practical, sustainable, enforceable, readily understood and developed in concert with national stakeholders, 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.[56]

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associated risks to the environment (see FAO Biosecurity Toolkit, 2007). In the context of the Convention on Biological Diversity and Cartagena Protocol, biosafety refers to the means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health (see the Convention on Biological Diversity, Article 8(g)). Translation of the terms "biosafety" and "biosecurity" may further add to the confusion.

55 See BWC/MSP/2008/5, Report of the Meeting of States Parties, paragraph 20.

56 See BWC/MSP/2008/5, Report of the Meeting of States Parties, paragraph 20.

5.1 Scope of the national implementing measures

The measures to be taken by States Parties in the area of biosafety and biosecurity in furtherance of Article IV could entail the following:

5.1.1 Establishing a list of biological agents and toxins subject to control

An essential step in the development of biosecurity and biosafety measures will be to identify the biological agents and toxins of relevance to the BWC, including relevant animal, human, zoonotic, and plant pathogens and toxins, the handling of which is to be regulated and subject to controls.

For that purpose, States Parties should consider classifying biological agents and toxins into lists applying a risk-based approach, i.e. in consideration of the risks that the agents or toxins pose to public health and safety and national security, in order to subsequently determine the appropriate level of controls to be established with respect to any such agents and toxins. However, as mentioned above in Module IV, it should be recalled that any such lists are illustrative and do not reflect the comprehensive scope of the BWC which is rooted in the concept of the "general purpose criterion".

States Parties may decide to:

- Develop their own lists;
- Rely on existing lists as established at the international or regional levels; or
- Rely on lists established by other States Parties as a starting point in developing their own specific, tailored lists.

The decisions with respect to the list should be made in consultation with all relevant stakeholders and experts, and the list should be kept under regular review and revised as necessary. For that purpose, States Parties could consider setting up a specific body comprising experts (see below). In order to facilitate future revisions, the list should preferably be set at the regulatory level, rather than as part of the legislative measures so as to maintain future flexibility.

Box 35 – International control lists

As discussed in Module VI, there are existing lists for the purpose of export control, which States Parties could consider using when developing such lists (see Box 32).

The WOAH maintains a list of notifiable terrestrial and aquatic animal diseases. The WOAH list is updated by experts on a regular basis to include the latest threats, and includes all animal pathogens that might potentially be used as biological weapons. This list is available at https://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2020.

States Parties may also consider taking a risk or hazard group approach, under which biological agents are classified into "risk" or "hazard groups" based upon each agent's characteristics and epidemiological profile. The higher the risk or hazard group, the higher the likelihood that the agent will cause and spread infection in humans or animals in the country, and/or the more severe the consequences of that infection will be to individual and public health, if it were to occur.[57] Classical definitions for risk groups 1 to 4 are contained in the Third Edition of the WHO *Laboratory Biosafety Manual* (2004), available at https://www.who.int/publications/i/item/9241546506:

- Risk Group 1 (no or low individual and community risk)
  A microorganism that is unlikely to cause human or animal disease.
- Risk Group 2 (moderate individual risk, low community risk)
  A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
- Risk Group 3 (high individual risk, low community risk)
  A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
- Risk Group 4 (high individual and community risk)
  A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

American Biological Safety Association (ABSA) International maintains a Risk Group database referencing the risk classification level in various countries of specific biological agents. This database is available at: https://my.absa.org/Riskgroups

57 Source: *Laboratory Biosafety Manual*, Fourth Edition, WHO, 2020, p. 93

5.1.2 Establishing a national control regime for high-risk biological agents and toxins

For the purpose of implementing the requirement under Article IV to effectively prevent the development, production, use[58], stockpiling, acquisition, or retention of biological or toxin weapons, States Parties should consider subjecting the conduct of the activities involving those agents and toxins posing a high risk, as identified in the lists, to control.

Controlled activities could comprise the development, production, use, stockpiling, acquisition, or retention of biological agents or toxins, with each State Party determining the nature of the controls to be established depending on the type of agents and toxins involved.

Licensing or prior registration could be considered for controlling the activities involving the agents and toxins posing a high risk (i.e. equivalent to agents and toxins in WHO Risk Groups 3 and 4, or otherwise posing a high risk). Depending on the outcome of the risk assessment, some States Parties might also consider providing a basis for prohibiting certain activities which involve the most dangerous biological agents or toxins. For example, Canada prohibits activities related to the variola virus, in accordance with World Health Assembly resolutions.

Box 36 – Focus on Canada's implementing measures

Excerpts from the 2009 Human Pathogens and Toxins Act:[59]

"Controlled activities

7 (1) No person shall knowingly conduct any of the following activities unless a licence has been issued by the Minister that authorizes the activity:

(a) possessing, handling or using a human pathogen or toxin;
(b) producing a human pathogen or toxin;
(c) storing a human pathogen or toxin;

58 While Article IV itself does not refer to "use", the Fourth Review Conference in 1996 reaffirmed that "under all circumstances the use of bacteriological (biological) and toxin weapons is effectively prohibited by the Convention." See BWC/CONF.IV/9, Part II, paragraph 7.

59 The full text of the Act is available at: https://lois-laws.justice.gc.ca/eng/acts/H-5.67/FullText.html.

(d) permitting any person access to a human pathogen or toxin;
(e) transferring a human pathogen or toxin;
(f) importing or exporting a human pathogen or toxin;
(g) releasing or otherwise abandoning a human pathogen or toxin; or
(h) disposing of a human pathogen or toxin.

Other Acts

2) Subsection (1) does not apply to

(a) any activity to which the Transportation of Dangerous Goods Act, 1992 applies; or
(b) the export of human pathogens or toxins authorized under the Export and Import Permits Act.

Human pathogens and toxins — Schedule 5

8 Despite section 7, no person shall conduct any activity referred to in that section in relation to a human pathogen or toxin listed in Schedule 5.

[...]

SCHEDULE 5

(Subsection 3(1), sections 8 and 10 and subsections 12(2) and 71(1))
Prohibited Human Pathogens and Toxins
PART 1
Toxins
PART 2
Human Pathogens
Variola virus
Virus de la variole"

In order to comprehensively oversee the activities involving biological agents and toxins of relevance to the BWC, States Parties could also consider requiring **prior notification or registration with respect to activities involving agents and toxins posing a moderate or low risk** (i.e. equivalent to agents and toxins in WHO Risk Groups 1 and 2). This could also facilitate the establishment and maintenance of a national registry/inventory of relevant agents and facilities (see below).

Box 37 – Focus on Germany's implementing measures

Excerpts from the Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents of 15 July 2013, as amended in 2017:[60]

"**Section 15**

Licensing obligation

(1) The employer shall require a licence issued by the competent authority before first starting activities of protection levels 3 or 4 in laboratories, the husbandry of laboratory animals or biotechnology. The licence shall cover the physical, technical and organisational requirements pursuant to this Ordinance for the protection of employees and other persons against the hazards caused by such activities. Clause 1 shall also apply to healthcare facilities where activities of protection level 4 are to be performed. A licence shall not be required for activities involving biological agents of risk group 3 marked with (**).

[...]

Section 16

Notification obligation

(1) As specified in the provisions of paras. 2 and 3, the employer shall notify the competent authority of:

1. the initial start of

a) a specific activity involving biological agents of risk group 2,

b) an activity involving biological agents of risk group 3 insofar as such activities are not subject to the licensing obligations pursuant to section 15, in laboratories, the husbandry of laboratory animals and biotechnology,

[...]

(3) The notification pursuant to para. 1 nos. 1, 2 or no. 4 shall be made no later than 30 days prior to starting or discontinuing the activities, the notification pursuant to para. 1 no. 3 shall be made immediately."

60 The full text of the Ordinance is available at: https://www.gesetze-im-internet.de/englisch_biostoffv/englisch_biostoffv.html

While licensing, prior registration or other control requirements may need to be established at the legislative level, the details may be better placed in regulatory measures in order to maintain the flexibility to adjust the control framework to new risks, developments or considerations as they may arise in the future.

In view of the apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, genetic engineering, biotechnology, molecular biology and any applications resulting from genome studies, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, as recognised by consecutive Review Conferences,[61] any work involving genetically modified organisms and genetic modification of organisms could also be subject to the same requirements. For example, Australia, the Netherlands and the United Kingdom have already adopted measures to address that risk.

Exemptions could also be considered with respect to specific activities, for example to minimise instances of overlap and duplication with other measures or to recognise where there is little or no biosafety or biosecurity risk.

The licensing or registration procedure should also enable the relevant authorities to collect the data required for the annual CBM submissions (see Box 3) and the establishment of a national inventory of relevant laboratories and facilities (see below). As part of the licence application or registration, the following information should be sought: name of the applicant; location of the laboratory or facility; and the scope and general description of the activities foreseen to be conducted. Consideration should also be given to requiring regular reporting by the licensee or registered entity or individual regarding the activities conducted at the laboratory or facility.

61 See BWC/CONF.IV/9, Final Document of the Fourth Review Conference (1996), Part II, Article I, paragraph 6; BWC/CONF.III/23, Final Document of the Third Review Conference (1991), Part II, Article I, paragraph 3; and BWC/CONF.II/13, Final Document of the Second Review Conference (1986), Part II, Article I, paragraph 4.

5.1.3 Requiring compliance with biosafety and biosecurity standards

As part of the licensing conditions or requirements for the conduct of controlled activities involving listed agents or toxins, States Parties could consider requiring appropriate **accreditation or certification** of the laboratories or facilities at which the controlled activities will be conducted. More generally, such laboratories and/or facilities could be required to meet certain biosafety and biosecurity requirements and maintain a biorisk management system, as specified in relevant international, regional or national standards, manuals or guidelines such as:

- The WHO *Laboratory Biosafety Manual* (2020) and the WHO *Biorisk Management: Laboratory Biosecurity Guidance* (2006) (see Box 52).
- The ISO Standards, including *ISO 35001:2019 Biorisk management for laboratories and other related organisations*. For more information, please refer to the ISO website at https://www.iso.org/standard/71293.html
- The CEN Workshop Agreement *CWA15793:2011: Laboratory Biorisk Management* and the CEN Workshop Agreement *CWA16393:2012: Guidelines for the Implementation of CWA15793:2011*
- The CEN Workshop Agreement *CWA16335:2008: Biosafety Professional (BSP) Competence*

Included within such biosecurity measures should be requirements to establish and maintain appropriate **physical protection measures**, also referred as physical security measures. These should secure or otherwise physically protect biological agents or toxins in laboratories or other facilities, whether produced, used or stored, and during transportation, to prevent unauthorised access to biological agents and toxins. Such measures could entail the establishment of appropriate installations with restricted or controlled areas, with related access control measures and personnel authorisation, as well as other measures to detect unauthorised access or the theft, loss or release of biological agents or toxins.

Requiring the licensee or operator of the laboratory or other facility to establish and maintain a specific **biosecurity plan** could also be considered. Such a plan should be specific to the laboratory or facility requirements, to the type of work conducted, and to local and geographical conditions. The plan prepared and defined by the operator of the laboratory or facility can serve to increase awareness about the risks at the specific laboratory or facility, as well as to promote a culture of responsibility and encourage compliance.

States Parties such as Canada, Denmark and the United States have established such requirements in their legislation.

Box 38 – Focus on Canada's implementing measures

Excerpts from the 2015 Human Pathogens and Toxins Regulations:[62]

"Condition on issuance — risk management plan

3 If the applicant for a licence is a person who intends to carry out scientific research, the Minister must, before issuing the licence, determine that the person has developed a plan that sets out administrative measures for managing and controlling biosafety and biosecurity risks during the period in which the licence is in effect."

The Regulations define scientific research as follows:

"**scientific research** means the following types of systematic investigation or research that are carried out in a field of science or technology by means of controlled activities:

(a) basic research, when the controlled activities are conducted for the advancement of scientific knowledge without a specific practical application;

(b) applied research, when the controlled activities are conducted for the advancement of scientific knowledge with a specific practical application; and

(c) experimental development, when the controlled activities are conducted to achieve scientific or technological advancement for the purpose of creating new — or improving existing — materials, products, processes or devices. (*recherche scientifique*)"

62 The full text of the Regulations is available at: https://lois-laws.justice.gc.ca/eng/regulations/SOR-2015-44/page-1.html#h-823195

Box 39 – Focus on Denmark's implementing measures

Excerpts from the Executive Order on securing specific biological substances, delivery systems and related materials of 15 October 2009:[63]

"**Article 17. 1.** Entities which apply for permits are to prepare a vulnerability assessment and a security plan, which will be included in the permit application evaluation. The assessment and plan are to be prepared on a designated form which can be obtained from The Centre for Biosecurity and Biopreparedness or https://www.biosecurity.dk/english/resources/biosecurity-book/forms.

2. The security plan is to include:

1) Registration procedures in association with stocks.

2) Disposal procedures.

3) Accident procedures.

4) Access control systems.

5) Technical security barriers, including alarm systems, technical inspections of alarms etc.

6) Security evaluation of selected persons where required, cf. Article 14.

7) Securing of sensitive information, including storage of information relating to technology, storage of substances etc. and personnel and visit information (IT/document security).

8) Drills/training.

3. The security plan is to be maintained on an ongoing basis and must be available to The Centre for Biosecurity and Biopreparedness on request."

63 The text of this Executive Order is available in 22 different languages on the CBB website from https://sso.agc.gov.sg/Act/BATA2005?WholeDoc=1#pr36

Box 40 – Focus on the United States' implementing measures

Excerpts from the Code of Federal Regulations, Title 42: Public Health, Part 73—Select Agents and Toxins:

"§73.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control,

(2) Contain provisions for the control of access to select agents and toxins including the safeguarding of animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

(3) Contain provisions for routine cleaning, maintenance, and repairs,

(4) Establish procedures for removing unauthorized or suspicious persons,

(5) Describe procedures for addressing loss or compromise of keys, keycards, passwords, combinations, etc. and protocols for changing access permissions or locks following staff changes,

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records, and

(7) Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(8) Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of such activity.

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which manage security for the registered space are isolated or have controls that permit only authorized and authenticated users;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to spaces registered under this part or records in §73.17;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of this part are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments."

Additional requirements which States Parties might consider could include:

- The requirements for personnel to have **appropriate training** in biosafety and biosecurity, and proof of relevant qualifications, expertise and training.
- The requirement to designate a **biosafety/biosecurity officer**, also sometimes referred to as a biorisk officer.
- The requirement to establish an **institutional biosafety committee** to act as an independent review group for biosafety issues. This may include to review and approve proposed research and other activities conducted at the relevant institutions and involving the use of BW-related agents and toxins.

In order to minimise the potential threats coming from insiders having authorized access to high-risk agents and toxins, States Parties could also consider requiring **security clearance of personnel** working with certain listed biological agents and toxins.

Box 41 – Focus on the Russian Federation's implementing measures

Excerpts from the Russian Federation Chief Health Inspector Order No. 4, dated 28 January 2008, on Approval of Sanitary and Epidemiological Regulations, as amended on 2 June 2009:[64]

"2.2. Requirements regarding establishing personnel's clearance for work with group 3 and 4 pathogenic biological agents and regarding medical observation of personnel

2.2.1. Work with group 3 and 4 pathogenic biological agents may be performed by specialists who are at least 18 years of age and have the higher or secondary medical, biological, veterinary, or other education appropriate to the procedure for filling jobs that has been approved by each department and who have completed the appropriate courses of specialization (including mastery of methods for safe handling of group 3 and 4 pathogenic biological agents) and do not have any contraindications to vaccination, treatment with specific drugs, or working while in personal protective gear.

64 The full text of this Order is available on the VERTIC website at: https://www.vertic.org/media/National%20Legislation/Russian_Federation/RU_Regulations_Handling_Microorganisms.pdf

2.2.2. Clearance of personnel for work with group 3 and 4 pathogenic biological agents shall be granted on the basis of an order of the head of the organization that is issued once every 2 years with consideration for point 2.2.1 of this section and on the basis of verification of the personnel's knowledge of biological safety requirements. Training on compliance with biological safety requirements must be conducted at least once each year."

5.1.4 Establishing control measures over the transportation of high-risk agents and toxins

Measures could also be extended to the transportation of high-risk agents or toxins, including requiring that transportation be only: by an approved carrier holding appropriate authorisation delivered by the competent national authority; and in secure containers and in accordance with packaging, labelling and other requirements as set forth in the international and regional instruments governing the transport of dangerous goods. Requiring compliance with additional biosecurity measures (such as personnel clearance) could also be considered.

Box 42 – Outline of international and regional instruments governing the transport of dangerous goods

- **The UN Recommendations on the Transport of Dangerous Goods – Model Regulations.** The Model Regulations cover the classification of dangerous goods and their listing, the use, construction, testing and approval of packaging and portable tanks, and the consignment procedures (marking, labelling, placarding and documentation). For more information, see at https://www.unece.org/trans/danger/publi/unrec/rev13/13nature_e.html

- **The Regulation concerning the International Carriage of Dangerous Goods by Rail (RID).** This Regulation forms Appendix C to the Convention concerning International Carriage by Rail (COTIF) the Convention concerning International Carriage by Rail (COTIF) and applies to international traffic. For more information, see at https://otif.org/en/?page_id=1105

- **The International Maritime Dangerous Goods (IMDG) Code.** The IMDG Code was developed as an international code for the maritime transport of dangerous goods in packaged form, in order to enhance and harmonize the safe carriage of dangerous goods and to prevent pollution to the environment. For more information, see at https://www.imo.org/en/OurWork/Safety/Pages/DangerousGoods-default.aspx

- **The Technical Instructions for the Safe Transport of Dangerous Goods by Air**. The Technical Instructions contain a comprehensive set of requirements; among other things, they provide for the classification of dangerous goods and list these goods. The list identifies those goods which: a) are forbidden under any circumstances; b) are forbidden on both passenger and cargo aircraft in normal circumstances but could be carried in exceptional circumstances subject to exemption by the States concerned; c) are forbidden on passenger aircraft but permitted on cargo aircraft in normal circumstances; and d) are permitted on both passenger and cargo aircraft in normal circumstances. The Technical Instructions prescribe requirements for the packaging, as well as the markings and labels for packages and the documentation for consignments. For more information, see at https://www.icao.int/safety/DangerousGoods/Pages/Doc9284-Technical-Instructions.aspx

- **The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)**. According to Article 2 of the Agreement, dangerous goods barred from carriage by Annex A shall not be accepted for international transport, while international transport of other dangerous goods shall be authorised subject to compliance with:
    - the conditions laid down in Annex A for the goods in question, in particular as regards their packaging and labelling; and
    - the conditions laid down in Annex B, in particular as regards the construction, equipment and operation of the vehicle carrying the goods in question. For more information, see at https://www.unece.org/trans/danger/publi/adr/adr_e.html

- **The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)**. The Regulations annexed to the ADN contain provisions concerning dangerous substances and articles, provisions concerning their carriage in packages and in bulk on board inland navigation vessels or tank vessels, as well as provisions concerning the construction and operation of such vessels. For more information, see at https://www.unece.org/trans/danger/publi/adn/adn_e.html

An overview of the main issues to consider in the transport of biological agents and toxins, including a summary of the requirements for the categorisation, documentation, packaging and labelling of infectious substances for transport is provided in the fourth edition of the WHO *Laboratory Biosafety Manual* (2020).

5.1.5 Establishing offences and penalties

The legislative measures should establish offences and penalties in case of the undertaking of a controlled activity without complying with the requirements established by the implementing measures or as part of the licence conditions. Such offences and penalties may be of a penal nature. Administrative penalties could also be considered to encourage compliance with requirements.

Box 43 – Focus on France's implementing measures

"18. Any production, manufacture, transport, import, export, retention, gift, transfer, acquisition and use operation relating to micro-organisms and toxins included on the list defined in Article L. 5139-1 of the Public Health Code, as well as products containing them, is subject to an authorization.

19. Carrying out these operations without authorization is punished by three years in prison and a fine of €45,000.

20. The Order of 30 April 2012 sets the list of micro-organisms and toxins subject to authorization. This Order has two annexes:

- Annex I includes highly pathogenic micro-organisms and genetically modified micro-organisms which present the highest risks for public health;

- Annex II includes micro-organisms and toxins and genetically modified micro-organisms whose use would present a risk for public health. Annex II also defines the parts of these micro-organisms (genetic material) and includes the genetically modified organisms which have these parts."

Source: BWC/MSP/2013/MX/WP.16, dated 12 August 2013, National implementation assessment report of the Biological Weapons Convention (BWC), submitted by France

5.1.6 Designating and empowering relevant authorities

Laboratories or facilities possessing or storing BWC-relevant biological agents and toxins may be in various sectors (agricultural, medical, veterinary, etc.). The authority to administer the licensing or registration regime may not, therefore, always be centralized, and States Parties may share this responsibility between several existing entities (e.g. Ministry of Agriculture, Health, Industry, Research etc.).

Notwithstanding the authorities in charge of administering the respective licensing or registration regimes, as established by law, States Parties should consider designating a lead authority, specifying mandates for participating ministries and other governmental bodies, which would be responsible for ensuring effective enforcement and regular review of the implementing measures. Such an authority may already have been established to regulate related activities, such as activities in genetically modified organisms. States Parties could therefore consider enlarging the mandate of such an authority and review its composition to ensure appropriate representation.

Any such authority should be able to rely on technical expertise, such as medical expertise and in biology, engineering, law and social sciences, as well as on operational experience from the sectors concerned, including from law enforcement authorities.

Box 44 – Focus on Thailand's implementing measures

Excerpts from the Pathogens and Animal Toxins Act, B.E. 2558 (2015):[65]

"CHAPTER I PATHOGENS AND ANIMAL TOXINS COMMITTEE

Section 7. There shall be a committee called the "Pathogens and Animal Toxins Committee", consisting of:

(1) the Permanent Secretary of Ministry of Public Health as Chairperson;

(2) fourteen ex officio members, namely the Director-General of Department of Land Transport, the Director-General of Department of Foreign Trade, the Director-General of Department of Disease Control, the Director-General of Department of Fisheries, the Director-General of Department of Livestock Development, the Director-General of Customs Department, the Director-General of Department of Treaties and Legal Affairs, the Director- General of Department of International Organisations, the Secretary-General of National Research Council of Thailand, the Secretary-General of Office of Natural Resources and Environmental Policy and Planning, a representative of the Ministry of Defence, a representative of the Ministry of Science and Technology, a representative of the Office of the Council of State and a representative of the Office of the National Security Council;

(3) five qualified members appointed by the Minister from professionals having the knowledge and experience in pathogens or animal toxins, by and with the advice of the Medical Council of Thailand, the Veterinary Council of Thailand, the Medical Technology Council, the Pharmacy Council of Thailand and the Council of Science and Technology Professionals, one from each council;

(4) seven qualified members appointed by the Minister from persons having the knowledge, expertise, past performance records and experience in the fields of animal toxins, bacteria, molds, infectious diseases, viruses, parasites and biotechnology, one from each field.

The Director-General shall be a member and secretary, and the Director-General shall appoint two government officials of the Department of Medical Sciences who are responsible for the work related to pathogens or animal toxins as assistant secretaries.

The appointment of qualified members shall be in accordance with the criteria, procedures and conditions prescribed in the Notifications by the Minister."

65 The full text of the Act is available at: https://faolex.fao.org/docs/pdf/tha181044.pdf

▲ Meeting of the States Parties to the BWC, 22-25 November 2021. Photo credit: BWC ISU.

Box 45 – Focus on the United Kingdom's experience

Excerpts from the 2018 Biological Security Strategy:[66]

"**Strategy Implementation**

Minister responsible – Security Minister

Governance structure

Governance for much of the activity described in this strategy falls within departments' existing portfolios and governance mechanisms. This strategy brings together that activity to ensure that a cross-Government approach to biological security is maintained, while avoiding duplicating existing mechanisms and activities.

Many of the commitments can only be delivered if Government departments work together, in many cases across sectors that have not previously systematically engaged with one another. These commitments (as well as any new work or identified gaps that emerge when work on biological risks is being co-ordinated) will be owned by a cross-Government director-level governance board, made up of representatives from the following departments:

66 The full text of the Strategy is available at: https://www.gov.uk/government/publications/biological-security-strategy

- Home Office
- Department of Health and Social Care (DHSC) (including Public Health England (PHE) representation)
- Department for Environment, Food and Rural Affairs (DEFRA) (including Animal and Plant Health Agency (APHA) representation)
- Agri-Food and Biosciences Institute (AFBI)
- Ministry of Defense (MOD) (including Defence Science and Technology Laboratory (Dstl) representation)
- Foreign and Commonwealth Office (FCO) (including the Science and Innovation Network)
- Department for Business, Energy and Industrial Strategy (BEIS)
- Department for International Development (DFID)
- Government Ofice for Science (GO Science)
- Cabinet Office
- Health and Safety Executive (HSE)
- Office for Life Sciences (OLS)
- Department for International Trade
- the Devolved Administrations

This governance board will report to the Threats, Hazards, Resilience and Contingencies Subcommittee of the National Security Council, through the Security Minister, to ensure that a forum at the highest level of Government holds departments to account. The Government Chief Scientific Adviser will maintain an oversight of developments under the strategy."

The competent authorities designated to administer the control regime should be granted the necessary powers to conduct compliance verification, including powers of entry, inspection, search and seizure at relevant facilities or laboratories if required.[67]

67 See, e.g., Section 52 of Singapore's Biological Agents and Toxins Act 2005, available from the VERTIC website at: https://www.vertic.org/media/National%20Legislation/Singapore/SG_BWC_Act.pdf

5.1.7 Establishing measures to account for BWC-relevant biological agents and toxins

In order to enable States Parties to account for the BWC-relevant biological agents and toxins on their territory, at any given time, States Parties should consider establishing and maintaining a national inventory of such substances and toxins, as well as of the facilities in which they are kept.

Any such inventory should at a minimum include information on those facilities to be declared as part of the annual CBM submissions, that is, on:

- Each facility with maximum containment laboratories meeting the criteria for such laboratories as specified in the WHO *Laboratory Biosafety Manual*, Third Edition, and/or WOAH *Terrestrial Manual* or other equivalent guidelines adopted by relevant international organisations, such as those designated as Biosafety Level 4 (BL4, BSL4 or P4) or equivalent standards. If there is no BL4 laboratory in the country, or the WHO or WOAH system is not in use to categorise laboratories, consideration could be given to record information on the laboratories that handle pathogens that usually cause serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and where effective treatment and preventive measures are not usually available.
- Vaccine production facilities.

Box 46 – Focus on Uganda's experience in establishing a national inventory of dangerous pathogens

"The Republic of Uganda is one of the first countries to implement a national electronic database that assembles information collected from relevant Ugandan laboratories. This Ugandan Inventory of Dangerous Pathogens is different from an institute-specific pathogen inventory system, as it is intended to store the information collected from laboratories in the country working with dangerous pathogens in a centralized secure location.

[…]

Methods

[…]

Implementation process

The implementation of a National Inventory of Dangerous Pathogens can be divided into 3 stages: preparation, implementation, and maintenance. In the preparatory phase, the government of Uganda committed to the establishment of a National Inventory of Dangerous Pathogens and assigned responsibilities in the government.

With a designated government focal point in Uganda, the implementation phase was initiated, and a communication plan was set up for contacting the appropriate institutes for the relevant data. The list of these institutes was compiled with the help of IDI, UVRI, UNCST, NPHLS, and NADDEC, in addition to the Biosafety and Biosecurity Association Uganda, and included approximately 40 institutes being requested to provide relevant information. The decision of the prioritized pathogen list to be included in the inventory was determined to be the US Federal Select Agents List, and the information was gathered and inserted into the dedicated software. In the maintenance phase, the focal point is responsible for informing the appropriate Ugandan authorities (ie, the ministry of health, as part of the team for the JEE, and the Uganda representative at the BWC) about the number and location of institutes storing dangerous pathogens, as well as the variety of dangerous pathogens present in the Republic of Uganda and plans for annual updates of the inventory.

In all of these stages, communication, ownership, and data-collection activities lie with the Uganda focal point, and no sensitive information was shared with or handled by anyone not approved by the focal point. The database will be owned and controlled by the government of Uganda. Although institutional data on working with high-risk pathogens may not be sensitive information, the consolidated national data could be considered sensitive information and should therefore be stored safely and securely according to Ugandan procedures and relevant official information confidentiality laws."

Source: Sabrina Brizee, Musa Kwehangana, Collins Mwesigwa, Diederik A. Bleijs, Harold H. J. L. van den Berg, Evelien Kampert, Milton Wetaka Makoba, Atek Kagirita, Issa Makumbi, Francis Kakooza, Maxwell Otim Onapa, and Mark W. J. van Passel, "Establishment of a National Inventory of Dangerous Pathogens in the Republic of Uganda", in *Health Security*, Volume 17 Issue 3: 14 Jun 2019.

For the purpose of such an inventory, the implementing measures should impose related obligations to maintain registers/inventories and, as needed, reporting requirements on the operators of the relevant facilities.

Box 47 – Focus on Denmark's implementing measures

Excerpts from the Executive Order on securing specific biological substances, delivery systems and related materials of 15 October 2009:[68]

"*Registration and disposal of biological substances, delivery systems and related materials*

Article 18. The entity is to maintain registers/inventories of the biological substances, delivery systems and related materials included in this Executive Order for which it is responsible. The register/inventory is to be updated on an ongoing basis, at least once a quarter. Registers and other documents relating to permits are to be stored for a minimum of five years.

2. The entity is to report stock levels to The Centre for Biosecurity and Biopreparedness at least once a year. Stock movements are to be registered in accordance with the procedure stipulated by The Centre for Biosecurity and Biopreparedness.

3. The entity must make registers/inventories available to The Centre for Biosecurity and Biopreparedness on request."

▲ The Preparatory Committee for the Ninth Review Conference, 4-11 April 2022. Photo credit: BWC ISU.

68 The text of this Executive Order is available at: http://www.vertic.org/media/National%20Legislation/Denmark/DK_Executive_Order_Securing_Bio_Substances_EN.pdf

Box 48 – Focus on Singapore's implementing measures

Excerpts from the Biological Agents and Toxins Act 2005:

"Records and reporting requirements

44. Every operator of a facility shall —

(a) maintain an inventory of all biological agents and toxins at the facility, which shall include records of the following:

(i) the storage location of the biological agents and toxins;

(ii) the personnel having approval to access any of the biological agents and toxins, and the biological agents and toxins to which such approval relates;

(iii) the use to which the biological agents or toxins are to be and have been put;

(iv) the transfers of the biological agents and toxins within the facility and between the facility and any other facility;

(v) the inactivation of the biological agents;

(vi) the disposal of the biological agents and toxins; and

(vii) where the biological agents and toxins are First Schedule (Part II) biological agents, Second Schedule biological agents or Fifth Schedule toxins —

(A) the personnel who have dealt with the biological agents or toxins; and

(B) the personnel who have entered the area where the biological agents or toxins are used or stored"

The implementing measures should also:

- Provide for a mandatory requirement for an operator to immediately **report theft, loss, or release of controlled agents or toxins**, and introduce such a requirement also towards the public in general, as this will enable the competent authorities to ensure appropriate actions are taken in response, where required. The collection of data on reported incidents could also feed into the regular review of the national risk assessment, assist in the monitoring of national biosecurity and making recommendations for new measures as may be required, and prevent future incidents.
- Enable the competent authorities to control the internal movements of BWC-relevant agents and toxins within the country, and to ensure their safe custody during transportation (see Module V).

5.1.8 Addressing the risks posed by dual-use research of concern

Due to advances in biotechnology and the life sciences, research may reveal itself as being of dual-use concern. The 2014 Meeting of States Parties recognised that identifying research as being of dual-use concern does not, in itself, provide sufficient justification for proscribing or restricting its availability, or for preventing its pursuit. Identifying research as being of dual-use concern does however necessitate greater oversight, and for a collaborative and informed assessment of the potential benefits and risks of the research.[69] At the 2014 Meeting of Experts, in order to further seize opportunities for maximizing benefits from advances in science and technology while minimizing the risk of their application for prohibited purposes, States Parties also noted the value of enhancing national oversight of dual-use research of concern without hampering the fullest possible exchange of knowledge and technology for peaceful purposes. States Parties should ensure that national measures:

> (a) Provide for the frequent assessment of science and technology;
>
> (b) Minimize, to the extent possible, adverse impact on legitimate research;
>
> (c) Are transparent and commensurate with the risk;
>
> (d) Include flexible approaches that leverage existing review processes; and
>
> (e) Preserve and foster the benefits of research.[70]

69 See BWC/MSP/2014/5, Report of the Meeting of States Parties, paragraph 36.

70 See BWC/MSP/2014/5, Report of the Meeting of States Parties, Annex I, paragraph 16.

There is a variety of possible approaches to address the risks posed by dual-use research in the life sciences. Some States Parties may consider extending the control regime established over high-risk biological agents and toxins to related technologies when these are identified as being of dual use. Alternatively, or in conjunction with the application of controls, States Parties could consider raising awareness of research personnel concerning biosafety and biosecurity.

Box 49 – Focus on the United States' experience

"544. The U.S. Government has issued two policies for oversight of life sciences dual-use research of concern (DURC) to "preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research." The 2012 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern requires U.S. federal departments and agencies that fund life sciences research to identify and manage the risks associated with certain types of DURC, while the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern complements the 2012 policy by establishing institutional review processes and oversight requirements for institutions receiving federal funding for life sciences research. Together, the two policies support U.S. compliance with Article IV by engaging life sciences research institutions and federal funding agencies in shared responsibility to address the risk that knowledge, information, products, or technologies generated by DURC could be used for harm.

545. The U.S. Government advocates and conducts regular reviews of advances in science and technology to ensure its policies are sufficient to address potential risks. In October 2014, the U.S. Government announced a pause in new funding for gain-of-function (GOF) research on influenza, Middle East Respiratory Syndrome (MERS), or Severe Acute Respiratory Syndrome (SARS) viruses until completion of a deliberative process to review the risks and benefits of such research. As part of the process, the National Science Advisory Board for Biosecurity was charged to advise the U.S. Government on risk and benefit assessments for GOF research. Its recommendations on a conceptual approach to the evaluation of proposed GOF research were provided to the U.S. Government in May 2016."

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern is available at: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

(Addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented)

The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern is available at: http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf

(Establishes regular review of U.S. Government-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to mitigate risks as appropriate and collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC)

Source: BWC/CONF.VIII/INF.2, dated 21 October 2016, "Compliance by States Parties with their obligations under the Convention, Background information document submitted by the Implementation Support Unit"

5.2 Conducting a self-assessment and gap analysis

The importance of conducting a general self-assessment and gap analysis prior to the initiation of the BWC implementation process was outlined in Module I. The area of biosafety and biosecurity covered in this Module is one in which the conduct of such an assessment and analysis is critical for the development of measures fit for purpose, as well as to ensure that the adopted measures remain adequate and respond to the risks identified through this process.

Biosafety and biosecurity are concepts of relevance to a wide range of areas, such as human, animal and plant health, food, agriculture, and the protection of the environment. Assessing the risks which biological agents, toxins, related equipment, technologies and facilities stored on the national territory may pose to public health and national security, as well as identifying and evaluating the existing frameworks and the gaps at the national level may, therefore, require the involvement of a wide array of stakeholders in various sectors. These can include, for example: governmental entities with responsibilities in, *inter alia*, public health, environment, food safety, agriculture, animal health, and transportation at all state levels (national, subnational); and representatives of biomedical laboratories, veterinary laboratories, bioindustry, research centres, academia, farmers, etc.

The conduct of a self-assessment and gap analysis should be led by, and the responsibility of, a designated governmental authority. During the process, this authority should consult with all relevant stakeholders, as this will be mutually beneficial. While promoting a culture of responsibility, engaging with stakeholders will also inform about best practices and standards applied in the sectors concerned.

Box 50 – Additional resources for the conduct of a biosafety and biosecurity self-assessment and gap analysis

Several States Parties and organisations have developed tools to assist in the process of developing a biosafety and biosecurity framework, including for the conduct of risk assessment.

- The Public Health Agency of Canada has developed *An Analytical Approach for the Development of a National Biosafety and Biosecurity System*, a tool to strengthen global biosafety and biosecurity. The tool is available for use as both a downloadable manual and an online e-learning course in English and French at https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/analytical-approach.html
- At the 2014 Meeting of Experts, Chile, Colombia, Mexico and Spain made available, in English and Spanish, a questionnaire for evaluating facilities carrying out contained activities with biological agents. This questionnaire is contained in BWC/MSP/2014/MX/WP.6. It was developed to assess the suitability regarding the degree of biological containment and confinement measures applied to different biological agents in different laboratories, so as to gain a better understanding of the processes and standards applied while establishing the degree of risk inherent to handling such biological agents, and acquire relevant information on the facilities dealing with biological agents on a national level.
- Guidance on how to conduct a gap analysis for the purpose of assessing the existing state of biosecurity and identify biosecurity strengths and weaknesses can be found in a publication by the Danish Centre for Biosecurity and Biopreparedness (CBB), *An efficient and practical approach to Biosecurity*, which is available in English and Russian at https://www.biosecurity.dk/english/resources/biosecurity-book

- Under an Extended Assistance Programme initiated as part of EU Council Decision 2016/51 in support of the BWC, a "National Laboratory Biosecurity Assessment and Monitoring Checklist" was developed by Malaysia. The Checklist covers eight priority areas: management; biosecurity awareness; physical security; accountability for materials; information security; transport security; personnel reliability; and emergency response.

  The Checklist, and related information, can be found in an article by Sabrina Brizee et al. "Development of a Biosecurity Checklist for Laboratory Assessment and Monitoring", in *Applied Biosafety*, 1-7, ABSA International, 2019, available at http://coe-project53.istc.int/files/resources/8f23914ec4cfc57667dcbcc33862a2d5.pdf

- The Netherlands Biosecurity Office has developed two web applications that States Parties may find useful to use to identify vulnerabilities regarding biosecurity. These are the *Biosecurity Self-Scan Toolkit* and *Biosecurity Vulnerability Scan*, available in English from https://www.bureaubiosecurity.nl/en/node/541 and in Dutch from https://www.bureaubiosecurity.nl/toolkit The *Biosecurity Self-Scan Toolkit* is also available in French from https://outilevaluationbiosecurite.nl/home. The *Biosecurity Vulnerability Scan* is built around eight key areas: biosecurity awareness, personnel security, transport security, information security, control of materials, response plans, management, and physical security.

- Guidance on the conduct of a risk assessment to determine risk control measures, including an overview of the key considerations that apply in the risk ssessment framework, is provided in the fourth edition of the WHO *Laboratory Biosafety Manual* (2020), available at https://www.who.int/publications/i/item/9789240011311

- Guidance on the conduct of a national evaluation and survey of the existing regulatory environment as it relates to biomedical laboratory biosafety and biosecurity can be found in the *WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories: a Stepwise Approach*, available at https://apps.who.int/iris/handle/10665/332244. In particular, Table 2.1 provides a list of possible criteria for the conduct of an evaluation of the national or regional regulatory frameworks for laboratory biosafety and biosecurity.

- The WHO working paper *Life science research: opportunities and risks for public health: Mapping the issues* (2005) aims to identify the main issues associated with the potential misuse of life science research and development. It is available at https://apps.who.int/iris/handle/10665/69142

- The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences is developing a *Self-Assessment Framework*, intended to provide a measure of the organisational culture of biosafety, biosecurity, and responsible conduct to aid in the process of enhancing such a culture at the local level through baseline and periodic assessments. The January 2020 Working Draft is available at https://absa.org/wp-content/uploads/2020/02/Culture_of_Biosafety-Biosecurity_Self-Assessment_Framework.pdf

- The International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR) has developed the *Compendium of International Biosafety and Biosecurity Oversight Systems for Human and Animal Pathogens and Toxins*, which provides detailed descriptions of the national regulatory oversight approaches in the 11 IEGBBR member countries (Australia, Canada, Denmark, France, Germany, Japan, the Netherlands, Singapore, Switzerland, the United Kingdom and the United States). More information can be found at https://biosecuritycentral.org/resource/requirements-and-protocols/iegbbr-app/.

5.3 Complementary measures

Along with the measures taken at the legislative and regulatory levels, providing for a control regime over the high-risk agents and toxins, and related laboratories and facilities, complementary measures should be considered to promote a culture of responsible conduct by relevant stakeholders.

Certain measures as contained in the legislation or regulations may have been developed by or with the input of relevant stakeholders, facilitating future compliance. This may in particular be the case where compliance with specific professional standards, or biosafety or biosecurity management standards, is

required. The legislation or regulations may also prescribe actions to be taken by the operators of the relevant laboratories or facilities, at the organisational level, based on the specific requirement of their activities, such as the development of security plans, the conduct of regular risk assessment at the laboratory or facility, or the training of personnel.

Along with such measures, States Parties should encourage the adoption of codes of conduct and development of best practices, to promote a culture of responsibility amongst relevant stakeholders. More generally, States Parties should engage with private industry, universities, research centres and other stakeholders, including the public in general, by conducting awareness-raising, education and training. Any such measures may help to address the tensions between the necessary oversight of the activities posing a risk to public health and national security, and the need to preserve the economies, as well as to promote innovation and scientific and technological research and development. Such measures may also inform on how to mitigate biological risks.

Box 51 – Focus on South Africa's experience

"Continuing challenges: raising awareness

34. Despite the considerable involvement of scientists in South Africa's developing biosecurity regime, concerns remain regarding the extent of biosecurity awareness amongst scientists "in the labs". Similarly, to many other countries, biosecurity training has not been formalised within South Africa. Training in biosafety, biosecurity and bioethics is most commonly developed and administered 'in house', and may vary considerably between institutions. Similarly, the extent to which these topics are addressed in undergraduate and postgraduate curricula differs amongst teaching institutions. As a result, the life science community of South Africa – like many other countries – may be suggested to have highly variable levels of biosecurity awareness.

35. Without a comprehensive understanding of the levels of biosecurity awareness amongst scientists, it is difficult to speculate on how effectively they will engage with biosecurity legislation, perpetuate biosecurity practices within laboratories and raise biosecurity concerns. This, it is easy to see, may have implications for the robustness of any non-proliferation strategy.

36. In response to these concerns, the Academy of Science of South Africa launched a multifaceted project in 2013, to critically examine the current state of biorisk management in the South African life sciences. As part of this study, a survey was administered to life scientists working in public and private research facilities. This survey was an adapted version of a World Health Organization (2010) survey entitled 'Responsible life sciences research for global health security,' designed to canvass perceptions and understanding of biorisk management amongst life scientists.

37. The results of the survey highlight some of the concerns about biosecurity awareness. In particular, the survey raised awareness about problems relating to biosecurity education, and a perceived absence of communication between governmental policy makers and the scientific community. Some of the key findings from the survey are detailed in Box 16.4.

[...]

38. Such surveys demonstrate the continuing need for raising biosecurity awareness amongst scientists, and that biosecurity awareness cannot be presumed within the science population, despite the existence of comprehensive legislation. Identifying these issues provides a good baseline for future educational initiatives, enhanced strategies to protect whistleblowers, as well as enhanced communication strategies between policy makers and scientists.

39. As within the 'web of prevention' model, scientists play an important role as the 'first line of defence' in raising concerns about their own research – and that of others. Enhancing efforts to make scientists aware of key legislation, to make the legislation applicable (and implementable) in the working environment, and to protect anyone who would raise concerns, is thus vital for robust biorisk management, in which scientists play an effective role in mediating against biosecurity concerns.

Source: Louise Bezuidenhout, "Chapter 16: National implementation of biosecurity in South Africa", in *Preventing Biological Threats: What You Can Do. A Guide to Biological Security Issues and How to Address Them*, edited by Whitby S., Novossiolova T., Walther G. and Dando M., University of Bradford, 2015.

Box 52 – Additional resources for the development of biosafety and biosecrity measures

States Parties seeking assistance for the development of biosafety and biosecurity measures in furtherance of the BWC may refer to Annex 3 which lists resource materials which States Parties may find useful to consult, including model provisions as developed by VERTIC and regional organisations, legislation databases linking to actual legislative or regulatory texts adopted by States Parties for the implementation of the BWC, as well as self-assessment tools and training materials. Annex 4 provides further information on assistance programmes and initiatives.

In addition to the tools and resources referred to in Box 50 above, of specific relevance to this Module are the following.

Manuals and guidance documents

- The WHO *Laboratory Biosafety Manual, Fourth Edition* (2020) addresses biosafety core requirements, reflecting international standards and best practice in biosafety, as well, amongst others, as laboratory biosecurity. It is available at https://www.who.int/publications/i/item/9789240011311

- The WHO *Biorisk Management: Laboratory Biosecurity Guidance* (2006) provides detailed guidance on biosecurity within a biological laboratory and addresses its basic principles and best practices. It is available, in English and Japanese, at https://www.who.int/publications/i/item/biorisk-management-laboratory-biosecurity-guidance

- The WHO *Guidance on regulations for the transport of infectious substances 2019–2020* provides practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally. The Guidance is available in English, Farsi, French and Spanish from https://www.who.int/publications/i/item/WHO-WHE-CPI-2019-20

- The *WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories: A Stepwise Approach* aims to inform and support national legislative and executive authorities, policy-makers and regulators in creating, refining and implementing a regulatory framework for ensuring the highest standards of laboratory biosafety and biosecurity. This Guidance is available at https://apps.who.int/iris/handle/10665/332244

- A *Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences* was developed by the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences. The Guide provides information about training and educational resources related to the culture of biosafety, biosecurity, and responsible conduct in the life sciences. This Guide is available on the ABSA website at https://absa.org/wp-content/uploads/2019/04/CULTURE_TRAINING_CATALOGUE.pdf

- The publication *An Efficient and Practical Approach to Biosecurity*, was created by the Danish Centre for Biosecurity and Biopreparedness (CBB) as an aid to States that are still in the process of establishing national biosecurity systems. This publication is available, in English and Russian, at: https://biosecuritycentral.org/resource/core-guidance-and-recommendations/efficient-and-practical-approach-to-biosecurity/. In addition, CBB, with the Ministries of Defense, Foreign Affairs and Health, carries out the Danish Biosecurity Partnership Programme to contribute to the establishment of biosecurity and biopreparedness systems in selected countries in East Africa. The purpose of the Programme is to build legal frameworks and capacities to mitigate biological risks, as well as awareness raising of university students and researchers in life sciences. For more information, see https://www.biosecurity.dk/fileadmin/user_upload/PDF_FILER/Biosecurity_book/An_efficient_and_Practical_approach_to_Biosecurity_web1.pdf

- The publication *Preventing Biological Threats: What You Can Do A Guide to Biological Security Issues and How to Address Them*, produced by the Bradford Disarmament Research Centre in December 2015, is intended to raise awareness and knowledge of biological security. It is available, in English, French and Russian, at https://www.un.org/disarmament/biological-weapons/national-implementation/resource-repository.

- The *Guidelines for the implementation of Action B2 EU CBRN action plan, March 2014*, were prepared in order to assist EU Member States to implement the B2 action, as set forth in the EU CBRN Action Plan adopted in 2009 to strengthen CBRN security in the EU, and bring them into compliance with Security Council resolution 1540 (2004) and the BWC. This document is available at http://ebrf.eu/documents/Guidelines%20for%20the%20implementation%20of%20Action%20B2%20-%20March%202014.pdf.

- The Regulatory Guidelines developed by VERTIC for the implementation of the BWC address biosecurity and provide guidance on the establishment of control lists for biological agents, toxins, and dual-use equipment and technology, including intangible technology.[71] Available in Arabic, English, French, Georgian, Portuguese, Russian and Spanish at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

- The Biosecurity Resource Toolbox refers to resources addressing six biosecurity themes: guidance and best practices; legislation, policies and codes of conduct; self-assessment tools, frameworks and checklists; risk and threat assessment and management; biosafety and security training; and awareness raising. Available on the website of the European Biosecurity Regulators Forum (EBRF) at http://ebrf.eu/toolbox.html

71 At the time of writing, these Regulatory Guidelines were under revision.

Model provisions and samples of national implementing measures

- Model provisions for the legislative measures can be found in the Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 (2004)[72], developed by VERTIC and available in Arabic, Azeri, Bahasa Indonesian, English, French, Georgian, Mongolian, Portuguese, Russian and Spanish from https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

- Examples of biosafety and biosecurity legislation and soft law in selected States are listed in Annex to the *WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories: A Stepwise Approach*. Available at https://apps.who.int/iris/handle/10665/332244

- Texts of legislative and regulatory measures adopted by States Parties in the area of biosafety and biosecurity can also be accessed from the VERTIC BWC Legislation Database, available at https://www.vertic.org/programmes/nim/biological-weapons-and-materials/bwc-legislation-database/.

- A curated set of resources and tools applicable across the spectrum of biosecurity is available at Biosecurity Central. The site is designed to be easily searchable, includes a guided exploration workflow, and provides key details on a page describing each resource with direct access to the resources and tools wherever possible. It is available at https://biosecuritycentral.org/

72 At the time of writing, this Sample Act was under revision.

5.4 Possible synergies with other international instruments and initiatives

Biosafety and biosecurity issues fall within the remit of various international, regional and professional organisations. The measures required under the BWC in the area of biosafety and biosecurity overlap with measures that may be required for the implementation of the State Party's obligations under other international instruments. Pursuing biosafety and biosecurity measures under the BWC could, therefore, also contribute to the fulfilment of these other international obligations and instruments, such as the International Health Regulations (2005), relevant codes of the WOAH, the International Plant Protection Convention (IPPC), the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, or the FAO codes and guidelines.

A State Party may already have taken measures to implement these instruments and address biorisk management. Identifying and recognising such intercorrelations between various international instruments may be essential before engaging in the development process of any biosafety and biosecurity measure for the implementation of the BWC.

Box 53 – Outline of selected relevant international instruments

- **UN Security Council resolution 1540 (2004)**. Operative paragraphs 3(a) and (b) of resolution 1540 impose on UN Member States an obligation to take biosecurity measures by establishing appropriate domestic controls over biological agents and related materials to prevent their proliferation, including developing and maintaining appropriate effective accounting measures in production, use, storage or transport, as well as physical protection measures.

- **International Health Regulations (2005).** The purpose and scope of the International Health Regulations (IHR) are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". The IHR are applicable to all health risks, irrespective of origin or source. The IHR are available at https://www.who.int/ihr/publications/9789241580496/en/. The WHO reference document *Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties* is available at https://www.who.int/publications/i/item/who-hse-gcr-2013-2.

- **World Health Assembly resolutions.** Through various resolutions, the World Health Assembly addressed smallpox eradication and recommended the destruction of all variola virus stocks, with retention of the virus in only two repository centres in the Russian Federation and the United States for the purpose of further international research into antiviral agents and improved vaccines, and to permit high-priority investigations of the genetic structure and pathogenesis of smallpox. A list of relevant resolutions can be found at http://www.emro.who.int/health-topics/smallpox/information-resources.html.

- **The codes of the World Organisation for Animal Health (WOAH).**

    - The Terrestrial Animal Health Code (Terrestrial Code) provides standards for the improvement of animal health and welfare and veterinary public health worldwide, including through standards for safe international trade in terrestrial animals (mammals, reptiles, birds and bees) and their products. The Terrestrial Code is available at https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/.

    - The Aquatic Animal Health Code (Aquatic Code) provides standards for the improvement of aquatic animal health worldwide. It also includes standards for the welfare of farmed fish and use of antimicrobial agents in aquatic animals. The sanitary measures in the Aquatic Code should be used by the competent authorities of importing and exporting countries for the prevention, early detection, reporting and control of pathogenic agents in aquatic animals (amphibians, crustaceans, fish and molluscs) and to prevent their spread via international trade in aquatic animals and their products, while avoiding unjustified sanitary barriers to trade. The Code is available at https://www.oie.int/en/standard-setting/aquatic-code/

- The OECD Best Practice Guidelines on Biosecurity for Biological Resources Centres (BRCs) were endorsed by OECD member countries in March 2007. These Guidelines describe the methods and protocols for the secure maintenance and provision of biological materials. They are available in English and Spanish from http://www.oecd.org/sti/emerging-tech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm

MODULE VI – PREPAREDNESS AND RESPONSE FOR BIOEMERGENCIES (MEASURES RELEVANT TO ARTICLE VII)

Pursuant to Article VII of the BWC, each State Party to the Convention "undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention".

Being aware that an outbreak of disease may need an urgent response which cannot wait for a political decision by the Security Council, the States Parties agreed at the Seventh and Eighth Review Conferences that in view of the humanitarian imperative, pending consideration of a decision by the Security Council, timely emergency assistance could be provided by States Parties, if requested.[73]

Several Review Conferences have also noted that State Parties' national preparedness contributes to international capabilities for response, investigation and mitigation of outbreaks of disease, including those due to alleged use of biological or toxin weapons.[74]

The Seventh and Eighth Review Conferences further noted the need for States Parties to work nationally, and jointly, as appropriate, to improve, in accordance with their respective circumstances, national laws and regulations, their own disease surveillance and detection capacities for identifying and confirming the cause of outbreaks and cooperating, upon request, to build the capacity of other States Parties.[75]

73 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article VII, paragraphs 35 and 43; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraphs 33 and 38.

74 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article VII, paragraph 40; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraph 38; and BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article VII, paragraph 35.

75 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article VII, paragraph 44; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraph 39.

The range of national implementing measures that may be taken to adequately prepare for, detect and respond to disease outbreaks, including those of security concern, is wide. The information presented in this Module is therefore not intended to be exhaustive but instead concentrates on those measures that may be required to be taken at the legislative, regulatory or administrative levels.

6.1 Scope of the national implementing measures

In determining the exact scope and type of measures needed, each State Party should conduct a threat and risk assessment, as well as an evaluation and assessment of national capabilities and a gap analysis of the measures already in place in the country to prevent, detect and respond to emergencies. In doing so, States Parties should assess whether such measures are sufficient and adequate to respond to public health emergencies which may result from an event involving biological agents or toxins relevant to the BWC. In the conduct of such an assessment, developments in science and technology and related emerging biological threats should be considered. Many States Parties may already have undertaken such assessments in the context of the WHO's Joint External Evaluations.

The measures to be taken by States Parties in the area of bioemergency preparedness and response could entail the following:

6.1.1 Preparedness: Establishing an effective national infrastructure for disease surveillance and detection

Preparedness includes actions taken in advance to cope with anticipated problems and covers wide subject areas. The Seventh and Eighth Review Conferences recognised that capabilities to detect, quickly and effectively respond to, and recover from, the alleged use of a biological or toxin weapon need to be in place before they are required.[76]

Module VI outlines measures which States Parties could consider to ensure proper monitoring and detection of accidental or deliberate release of high-consequence biological agents and toxins at relevant laboratories and other facilities. In addition to any such measures, developing an effective national infrastructure for human, animal and plant disease surveillance and detection may contribute to improving preparedness.

76 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article VII, paragraph 45; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraph 40.

Thus, States Parties could consider:

- Establishing a national surveillance mechanism system, to record infectious diseases as well as incidents involving biological agents and toxins.
- Designating the competent authority responsible for the maintenance of such a mechanism.
- Setting requirements for operators of laboratories or other facilities to monitor and notify the competent authorities of incidents involving high-risk biological agents or toxins.
- Requiring health and veterinary professionals to notify and report on specific diseases, pathogens or events posing a threat to public health.

Any such measures may need to be supported by technical capabilities to detect disease outbreaks and incidents involving high-risk biological agents and toxins, including cost-effective rapid diagnostic tests.

Box 54 – Focus on Iceland's measures

Excerpts from Regulation on reporting of communicable diseases and agents posing a threat to public health, No. 221/2012, as amended by Regulation No. 816/2012:[77]

"CHAPTER I

On the duty to report.

Article 1.

The Chief Epidemiologist for Iceland is responsible for keeping a disease register covering infectious diseases, their causes, diseases caused by chemicals and radioactive agents, by unusual and unexpected events which may pose a threat to public health internationally, the consumption of antimicrobial agents, and vaccinations, cf. the Icelandic Regulation on Vaccinations.

[...]

77 The full text of the Regulation is available at https://www.government.is/media/velferdarraduneyti-media/media/Reglugerdir-enska/Regulation-on-reporting-of-communicable-diseases-and-agents-posing-a-threat-to-public-health-No-221-2012-as-amended.pdf

Article 2.

Those diseases, pathogens and events that are covered by the Act on Health Security and Communicable Disease Control are subject to notification (notifiable diseases) and, should they pose a threat to public health, they are also subject to the reporting of personally identifiable data (reportable diseases).

Notification duty refers to the duty to submit data to the Chief Epidemiologist without personal identity while the reporting duty refers to the duty to submit data on diseases with personal identity.

Article 3.

Physicians are obliged to register data on notifiable diseases and reportable diseases on special forms or electronically, according to instructions given by the Chief Epidemiologist, cf. Article 1. The same applies to directors of laboratories, directors of health care departments, and institutions. Registers on communicable diseases shall be sent to the Chief Epidemiologist every month or more frequently if he deems it necessary.

Physicians and nurses are obliged to register all vaccinations they perform in the patient record, according to further instructions given by the Chief Epidemiologist, cf. Article 1. Physicians report to the Chief Epidemiologist on performed vaccinations.

[**Chapter II** provides a list of notifiable diseases

Chapter III provides a list of reportable diseases, their pathogens and events posing threats to public health]

Article 6.

Notification on a reportable disease, pathogen or events posing a threat to public health shall be submitted without delay to the Chief Epidemiologist or according to his further instructions. The Chief Epidemiologist may, cf. provisions of Regulation on Health Security Measures, delegate to out-patient clinics and laboratories the role of keeping registers on reportable diseases and pathogens.

The registration form shall provide the following information:

1. Name of the disease or its pathogen and the code of diagnosis according to the International Classification of Diseases (ICD 10).

2. When, how, and which diagnosis of disease or pathogen was confirmed.

3. Personal identity of the infected.

4. The current residence of the infected.

5. Name of the reporter, physician's licence number, work place, signature and the date of reporting."

Box 55 – Focus on Slovakia's implementing measures

Excerpts from Act of 28 March 2007 on the Prohibition of Biological Weapons and on Amendments and Supplements to Certain Acts:[78]

"Article 4

1) Anyone finding materials or things that can be presumed to be exploited as a biological weapon or to contain highly hazardous biological agents or toxins, or discovering the leakage of such biological agents and toxins into the air and the environment shall be obliged to notify this fact without undue delay to the Police Force, the emergency call operation centre 2, the Public Health Care Authority of the Slovak Republic 3 (hereinafter referred to as the "Authority") or the Regional Public Health Care Authority in Banská Bystrica[4] (hereinafter referred to as the "Regional Authority"). The State authority that has received such notification shall without unnecessary delay inform the other State authorities referred to in the preceding sentence and the Slovak Intelligence Service accordingly. If finding such materials or things to be contained in a postal consignment, the notification duty shall be performed by the universal service provider, with the consignor being held accountable for the content of the postal consignment itself.

(2) When finding a facility or ascertaining the loss of highly hazardous biological agents or toxins, the provision of paragraph 1 shall be applied.

78 The full text of this Act is contained in BWC/MSP/2007/MX/WP.14, dated 22 August 2007, "Ways and Means to Enhance National Implementation of the Biological Weapons Convention (BWC) in Slovakia", submitted by Slovakia.

(3) A person who does not hold a licence for handling highly hazardous biological agents and toxins that has been issued by the Authority (hereinafter referred to as the "Licence") or a licence pursuant to a special regulation and, when carrying out their activities, isolates or detects highly hazardous biological agents or toxins shall be obliged to notify the Regional Authority thereof without undue delay"

6.1.2 Preparedness: Establishing an appropriate organisational structure to coordinate response and investigation of unusual disease outbreaks and biological incidents

In order to ensure an efficient and effective response to an outbreak at the earliest possible point, it is essential that States Parties be prepared, as the primary responsibility for assisting its population resting with the State Party.[79]

As outlined in Module V, there is a variety of actors which have a primary interest in biosecurity, including the ministries and governmental agencies responsible for public health, trade, transport, defence, law enforcement, agriculture, forestry, fisheries, food safety, and the environment. The same actors and additional ones such as for example in the tourism area will equally have an interest in addressing biological emergencies as they may arise. In addition to these, first responders, laboratory services and hospitals, as well as the public in general are also primarily concerned and have a vital role to play in the event of disease outbreaks.

An effective response to disease outbreaks or other events involving the release of high-consequence biological agents and toxins requires efficient coordination among relevant actors, and States Parties have recognised the particular importance of ensuring a coordinated response from the law enforcement and health sectors. States Parties further noted the value of working, in accordance with their national laws and regulations, to improve effective cooperation between these sectors, including by fostering mutual awareness, understanding, and improved information exchange, and by undertaking joint training activities.[80]

An national organisational structure could consist of the following:

- A dedicated command, communications and control operations centre for coordination and monitoring of unusual outbreak/biological incident operations;
- A multidisciplinary/multisectoral rapid response team; and
- Support by technical experts

79 See BWC/MSP/2014/5, Report of the Meeting of States Parties, dated 15 December 2014.

80 See BWC/MSP/2010/6, Report of the Meeting of States Parties, dated 17 December 2010, paragraph 25.

Such a structure may play an important role in ensuring a coordinated government approach to emergency management, and adequate preparedness and response to natural and intentional outbreaks of diseases caused by biological agents and toxins relevant to the BWC.

It is equally important to develop and maintain national technical capabilities, such as detection/diagnostic capabilities, and to have an established network of laboratories on which to rely to deal with disease outbreaks or other events involving the release of biological agents or toxins. Recognizing the resource challenges faced by many countries, it should be emphasized that stand-alone capacities are seldom required, instead use can be made of existing national capacities for dealing with natural disease outbreaks. The rapid identification of the agents or toxins and the early detection of emerging infectious diseases may be critical to inform the actions to be taken and prevent the spreading of the agents and appropriately respond to their effects.

While the institutional framework for dealing with bioemergencies does not necessarily need to be set forth at the legislative or regulatory levels, it is nonetheless important that this framework be set forth in writing and made available to all relevant stakeholders. Appropriate training of all those with a role to play in dealing with a bio-emergency, including through table-top or live exercises, is also essential to ensure timely and adequate response at the time of an actual event.

Box 56 – Focus on Denmark's experience

The Centre for Biosecurity and Biopreparedness (CBB) is responsible for preventing biological weapons (BW) development and responding to biological threats.

As part of its biopreparedness responsibilities, CBB:

- Carries out threat and risk analyses of scientific, technical, and general character. These analyses guide relevant biopreparedness efforts.
- Conducts modelling of potentially affected areas in the event of a suspected biological attack or accidental release.
- Maintains a 24/7 preparedness capability. The CBB preparedness organisation consists of an on-call Senior Medical Doctor with specialisation in microbiology and a Field Investigation Team. The tasks of the Field Investigation Team are to collect information,

collect samples, to conduct rapid laboratory analysis, and to provide expert medical advice in order to identify biological warfare agents, verification of dispersion area, and clinical advice on immediate actions to be taken including medical countermeasures. Furthermore, foreign specialist laboratories with BSL 4-facilities are included in the 24/7 preparedness capability.

- Conducts training and education both internally and with other agencies, develops and maintains concepts of operations under different circumstances, and maintains the necessary equipment.

When a biological incident is suspected, whether it is a Type 1-incident (primary attack) or a Type 2-incident (disease outbreak), CBB conducts a scientifically-based threat assessment as a basis for the investigational effort, and a coordinating group is established at CBB. The same procedure is carried out for accidental releases of dangerous biological agents (Type 3-incidents), but instead of a threat assessment, a risk analysis is conducted. The investigation makes use of a number of tools and scientific capabilities. CBB's incident report contains an overall conclusion of the investigation and provides relevant expert advice in relation to mitigating threats and risks. In this process, CBB, amongst other things, carries out the following tasks:

- **Medical intelligence.** CBB collects relevant information to analyze the incident; partly from the Centre's own sources, and partly from other parties.
- **Clinical picture**. CBB obtains information about potential illness in connection with the incident – presentation of symptoms, course of disease, and paraclinical results.
- **Epidemiological situation**. In connection with a possible disease outbreak, CBB collects information about the epidemiological situation.
- **Sampling.** Collection of samples from the environment, or, if possible, from clinical material from animals and humans takes place nationally by activating CBB's Field Investigation Team. The team takes samples for subsequent analysis.
- **Laboratory Analysis**. Laboratory analysis takes place at CBB's laboratory facilities, which are manned by a 24-hour duty officer. If necessary, CBB can also draw on external specialist laboratories with BSL 4-facilities.

- **Dispersal Analysis.** CBB demarcates the contaminated area, and identifies potentially exposed individuals, among other things by using an advanced dispersal analysis system.
- **Diagnosis.** CBB collects all information and analysis results in an overall report that seeks to identify the cause of the incident and provide a prognosis for further progression (consequences, dangerousness, etc.).
- **Countermeasures.** If necessary, the report includes recommendations for countermeasures, both medical (e.g. medical treatment or preventive vaccination), and physical (e.g., personal protective equipment, cordons, and decontamination).
- **Information.** If necessary, the report from CBB will include draft information for the press, potentially exposed persons or others, and, if necessary, CBB assists by informing other authorities.

Source: CBB website (https://www.biosecurity.dk/biopreparedness/biopreparedness-tasks).

6.1.3 Preparedness: Developing national emergency management plans

Planning for biological emergencies underpins preparedness. States Parties should, therefore, adopt national emergency or contingency plans to respond to disease outbreaks. Some States Parties have specifically required the adoption of such plan through legislation, also designating the leading authority in this area.

Plans should be fit for purpose, and consider all relevant types of hazards, including those affecting human and animal health as well as agriculture, livestock and the natural environment. Plans should also consider high-impact events such as epidemics and pandemics.

Plans should be adapted to available resources and the local context. They should be tested and reviewed regularly to ensure that they are operational and fit for purpose.

Such plans could provide for measures to be taken in response to and in the aftermath of a disease outbreak, such as for example decontamination, but also in advance of such outbreak, such as maintaining stocks of vaccines and antimicrobial drugs or any other necessary material and equipment.

In developing such plans, areas requiring additional regulation may emerge, and specific measures may need to be adopted to govern the activity in

question (decontamination standards, laws allowing for quarantine, etc.). It may also make apparent those areas where capabilities or capacities are lacking. This will inform the authorities about the areas in which assistance may be required in the event of a disease outbreak or biological incident and should prompt actions to secure such assistance where required (see below).

Since 2016, the WHO has been working closely with many countries and its partners to support the development of National Action Planning for Health Security (NAPHS). NAPHS is a country owned, multi-year, planning process that can accelerate the implementation of IHR core capacities, and is based on a One Health for all-hazards, whole-of-government approach. The WHO secretariat has developed the NAPHS framework to consolidate technical guidance to countries for the development and implementation capturing feedback from countries, regions and partners.

Examples of animal health emergency management plans and other resources to support emergency planning can be found on the WOAH website at https://www.oie.int/en/solidarity/emergency-management/planning-for-emergencies/.

Box 57 – Focus on the United States' measures

Excerpts from Public Health Security and Bioterrorism Preparedness and Response Act of 2002, amending the Public Health Service Act (42 U.S.C. 201 et seq.):[81]

"SEC. 2801. NATIONAL PREPAREDNESS PLAN.

"(a) IN GENERAL.

"(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—The Secretary shall further develop and implement a coordinated strategy, building upon the core public health capabilities established pursuant to section 319A, for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies, including the preparation of a plan under this section. The Secretary shall periodically thereafter review and, as appropriate, revise the plan.

"(2) NATIONAL APPROACH. In carrying out paragraph (1), the Secretary shall collaborate with the States toward the goal of ensuring that the activities of the Secretary regarding bioterrorism and other public health emergencies are coordinated with activities of the States, including local governments.

[…]

81 The full text of this Act is available at: https://www.selectagents.gov/resources/docs/PL107-188.pdf.

''(b) PREPAREDNESS GOALS. The plan under subsection (a) should include provisions in furtherance of the following:

''(1) Providing effective assistance to State and local governments in the event of bioterrorism or other public health emergency.

''(2) Ensuring that State and local governments have appropriate capacity to detect and respond effectively to such emergencies, including capacities for the following:

''(A) Effective public health surveillance and reporting mechanisms at the State and local levels.

''(B) Appropriate laboratory readiness.

''(C) Properly trained and equipped emergency response, public health, and medical personnel.

''(D) Health and safety protection of workers responding to such an emergency.

''(E) Public health agencies that are prepared to coordinate health services (including mental health services) during and after such emergencies.

''(F) Participation in communications networks that can effectively disseminate relevant information in a timely and secure manner to appropriate public and private entities and to the public

''(3) Developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies.

''(4) Ensuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency.

''(5) Enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies.''

Information on the United States' approach to preparedness, detection, and response to agricultural threats can also be found in BWC/MSP/2019/MX.4/WP.1, 15 July 2019.

6.1.4 Response: Taking measures to enable and/or facilitate the provision or receipt of assistance and protection

In the context of biological agents, response deals with minimizing the effects on life in a disease situation or in other situations involving the release of high-consequence biological agents or toxins. This covers the mobilisation and organisation of personnel and material resources and should be based on planning and preparation before an event takes place.

In a bioemergency situation, States Parties may require assistance in the form of expertise, financial assistance, information, protection, detection, decontamination, prophylactic and medical and other equipment. Ensuring timely access without restrictions to affordable drugs and vaccines and related diagnostic tools, and preventive and therapeutic equipment is crucial.

In the preparation of the emergency management plan referred to above, specific gaps and needs for specific type of assistance may have been identified. States Parties anticipating needs for assistance and States Parties in a position to provide such assistance could therefore consider entering into agreements or arrangements to spell out the procedure and facilitate the provision and receipt of assistance where required.

As has been recognised by States Parties, there may be legal, regulatory and logistical challenges to providing and receiving international assistance. States Parties could, therefore, consider taking measures to:

- Waive or enable the recognition of medical credentials, licences, and professional certifications of personnel when sent by a foreign State to provide emergency assistance in case of a disease outbreak;
- Exempt the transfer or transportation of biological agent, pathogen, animal and human clinical samples relevant to the BWC from certain control requirements where such samples are required as part of the emergency response;
- Enable the provision, without restrictions, of means of protection against, and responses to, the use of biological or toxin weapons to the requesting State Party, including clearance to import into or use medical products in the country;
- Ensure liability protections for medical providers or those who manufacture, distribute or administer medical countermeasures.

Some of the measures to address these challenges may need to be adopted at the legislative or regulatory levels. Others may take the form of technical cooperation and assistance agreements among States Parties.

6.1.5 Response: Facilitating investigations

In order to determine the cause of an infectious disease outbreak or other event involving the accidental or deliberate release of high-consequence biological agents or toxins, an investigation should be conducted, relying on appropriate expertise, such as from experts in the public health sector, laboratories, law enforcement authorities, and microbial forensics.

Specific measures may be required to facilitate the collection of evidence, for example:

- Such investigations will certainly require the collection and analysis of environmental and biomedical samples. Procedures for sampling and analysis should therefore be established, taking into account confidentiality and integrity requirements, including the need to ensure a proper chain of custody as samples taken could serve as evidence in future legal proceedings.
- The establishment of appropriate arrangements with other States Parties to facilitate the sharing of samples, where required, could also be considered.
- Relevant procedures should ensure appropriate coordination and communication between health and law enforcement authorities.
- Concluding mutual legal assistance arrangements with other States Parties should also be considered in order to facilitate the collection of evidence that may need to be obtained from abroad.

6.2 Possible synergies with other international instruments and initiatives

Several international and regional instruments deal with biological emergency planning and response, and many initiatives are steered by interested international and regional organisations and partnerships.

The Seventh and Eighth Review Conferences thus noted that "the International Health Regulations (2005) are important for building capacity to prevent, protect against, control and respond to the international spread of disease; such aims are compatible with the objectives of the Convention."[82]

82 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article VII, paragraph 44; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraph 39.

Box 58 – Outline of the International Health Regulations (2005)

The IHR aim to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

The IHR provide a framework for the prevention, detection and containment of public health risks at source, before they spread across borders, through the collaborative actions of States Parties and the WHO.

Notification is required under the IHR for all "events that may constitute a public health emergency of international concern".

The IHR emphasize the importance of national capacities and require WHO Member States to develop, strengthen and maintain the capacity to detect, assess, notify and report events in accordance with the Regulations.[83]

The WHO IHR Monitoring and Evaluation Framework consists of four components: one mandatory (annual reporting) and three voluntary (joint external evaluations, after action reviews and simulation exercises).

IHR States Parties have to report annually to the World Health Assembly (WHA) on the implementation of capacity requirements under the IHR. To support IHR States Parties in this task, the WHO has launched a web-based platform, the Electronic State Parties Self-Assessment Annual Reporting Tool (e-SPAR). The tool consists of 35 indicators for the 15 IHR capacities needed to detect, assess, notify, report and respond to public health risk and acute events of domestic and international concern. For each of the 15 capacities, one to three indicators are used to measure the status of each capacity. The e-SPAR tool is accessible at https://extranet.who.int/e-spar

The joint external evaluation is a voluntary, collaborative, multisectoral process to evaluate country capacity to prevent, detect and rapidly respond to public health risks occurring naturally or due to deliberate or accidental events. The purpose of the evaluation is to evaluate country-specific status, progress in achieving the core capacity requirements under Annex 1 of the IHR, and recommend priority actions to be taken across the 19 technical areas being evaluated.

83 See Article 5 of the International Health Regulations.

The Sendai Framework for Disaster Risk Reduction 2015-2030 was adopted at the Third UN World Conference on Disaster Risk Reduction in 2015. The Framework applies to the risk of small-scale and large-scale, frequent and infrequent, sudden and slow-onset disasters, caused by natural or manmade hazards as well as related environmental, technological and biological hazards and risks. It aims to guide the multi-hazard management of disaster risk in development at all levels as well as within and across all sectors. There are four priorities for action to prevent new and reduce existing disaster risks: (i) Understanding disaster risk; (ii) Strengthening disaster risk governance to manage disaster risk; (iii) Investing in disaster reduction for resilience and; (iv) Enhancing disaster preparedness for effective response, and to "Build Back Better" in recovery, rehabilitation and reconstruction.

Consecutive BWC Review Conferences have acknowledged the coordinating role which the United Nations could play in providing assistance in case of a biological emergency, with the help of States Parties, as well as other intergovernmental organisations, in accordance with their respective mandates, such as the World Health Organization (WHO), the World Organisation for Animal Health (WOAH), the Food and Agriculture Organization of the United Nations (FAO), and the International Plant Protection Convention (IPPC).[84]

Information on the work of these organisations as well as some others which might be involved in the provision of assistance relevant to Article VII[85] was submitted by the Implementation Support Unit in 2014 and 2015 to assist States Parties' discussions on how to strengthen the implementation of Article VII.[86] Further background information, including a list of the Working Papers presented by States Parties between 2012 and 2017 on the issue of assistance, response and preparedness, was provided in BWC/MSP/2018/MX.4/2.

84 See e.g. BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article VII, paragraph 36; and BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article VII, paragraph 34.

85 Such as: the International Committee of the Red Cross (ICRC), the International Federation of Red Cross and Red Crescent Societies (IFRC), the Organisation for the Prohibition of Chemical Weapons (OPCW), the UN Office for the Coordination of Humanitarian Affairs (UNOCHA), and UNODA.

86 See BWC/MSP/2014/MX/INF.1, dated 2 June 2014; BWC/MSP/2014/INF.2, dated 21 October 2014; BWC/MSP/2015/MX/INF.4, dated 29 June 2015

Box 59 — Additional resources for the development of biopreparedness and bioemergency response measures

States Parties seeking assistance for the development of biopreparedness and emergency response measures may refer to Annex 3 which lists resource materials which they may find useful to consult, including model provisions as developed by VERTIC and regional organisations, legislation databases linking to actual legislative or regulatory texts adopted by the States Parties for BWC implementation, as well as self-assessment tools and training materials. Annex 4 provides further information on assistance programmes and initiatives.

Of specific relevance to this Module are the following:

- The Regulatory Guidelines developed by VERTIC for BWC implementation[87]. These Guidelines provide guidance on the establishment or designation of governmental bodies responsible for implementation of the BWC and biological incident response, as well as on the establishment of a mechanism to respond to any biological incidents, whether intentional or accidental that could have a harmful or deadly impact on human, animal or plant health. These Guidelines are available at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

- In 2019, the Danish Centre for Biosecurity and Biopreparedness (CBB) published *An Introduction to Biopreparedness*, which describes an effective way to investigate and respond to incidents involving hazardous biological substances, provides information on biological threats and offers some strategies for dealing with the aftermath. This book is available at https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Andre/CBB_Biopreparedness_book_accessability_red_secure.pdf

- The International Federation of the Red Cross and Red Crescent Societies (IFRC) has produced three key guidance documents that have been endorsed by resolutions of the International Conference of the Red Cross and Red Crescent:

87 At the time of writing, these Guidelines are under revision.

- the *Introduction to the Guidelines for the domestic facilitation and regulation of international disaster relief and initial recovery assistance (IDRL Guidelines)* at https://disasterlaw.ifrc.org/media/1327;

- the *Checklist on Law and Disaster Risk Reduction* (the *DRR Checklist*) at https://disasterlaw.ifrc.org/media/1354; and

- the *Checklist on Law and Disaster Preparedness and Response* (the *DPR Checklist*) at https://disasterlaw.ifrc.org/media/1287.

- The IFRC also maintains a disaster law database. All these tools are available at https://disasterlaw.ifrc.org/disaster-law-database.

- The IFRC publication *Guidance on Law and Public Health Emergency Preparedness and Response* is intended to serve as an assessment tool to support the review and updating of laws, policies and plans relating to public health emergencies. The *Guidance* has been designed to assist domestic decision-makers to identify critical legal and policy issues for consideration, and to evaluate how well those issues are currently addressed by existing instruments. The *Guidance* is available at https://disasterlaw.ifrc.org/sites/default/files/media/disaster_law/2022-05/20220410_LawPHE_Guidance.pdf.

- The WHO publication *Public Health Response to Biological and Chemical Weapons: WHO Guidance* (2004) includes information designed to guide preparedness for and response to the deliberate use of biological and chemical agents that affect health. The publication is available in Chinese, English, Japanese and Russian at https://www.who.int/publications/i/item/public-health-response-to-biological-and-chemical-weapons-who-guidance-(2004).

- The WHO *Protocol for Assessing National Surveillance and Response Capacities for the International Health Regulations (2005)* proposes guidance to IHR States Parties on the assessment of their national IHR core capacities for surveillance and response, in accordance with the core capacity strengthening requirements of Annex 1A of the IHR. This publication is available at https://www.afro.who.int/sites/default/files/2017-06/international_health_regulations_2005.pdf.

- The FAO has created the Good Emergency Management Practice (GEMP) as an overall approach to preparedness and response for animal health emergencies, to support its Member States in increasing preparedness to animal disease outbreaks and decreasing the time needed to respond to a crisis. In 2011, FAO published *Good Emergency Management Practice: The Essentials. A guide to preparing for animal health emergencies*. This Guide is available, in Arabic, Chinese, English, French, Russian and Spanish, at http://www.fao.org/documents/card/en/c/68b14f27-5234-51f3-b46e-8ecea0029d9b.

- In March 2018, the WOAH published *Guidelines for Investigation of Suspicious Biological Events* to assist national veterinary services in preparing for and investigating such events. These Guidelines are available at http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Guidelines_Investigation_Suspicious_Biological_Events.pdf.

- The United Nations Office for Disaster Risk Reduction (UNDRR) supports UN Member States in the implementation of the Sendai Framework for Disaster Risk Reduction 2015-2030. UNDRR has published guidelines designed to support countries in developing a national disaster risk reduction strategy aligned with the Sendai Framework. These are available at https://www.undrr.org/developing-national-disaster-risk-reduction-strategies. UNDRR also works with parliamentarians towards the development of disaster risk reduction and management legislation. For more information, see at https://www.undrr.org/implementing-sendai-framework-partners-and-stakeholders/parliamentarians.

States Parties could also find it useful to consider the national approaches adopted by others in the area of bioemergency preparedness and response. In addition to the legislation databases referenced in this *Guide*:

- A survey mapping the responsibilities for CBRNE emergency management in the Baltic Sea region States is available at https://cbss.org/wp-content/uploads/2020/04/CBRNE-management-in-BSR.pdf

- The United States issued the 2019 Biodefense Public Report, which is available at https://www.phe.gov/Preparedness/biodefense-strategy/2019-report/Documents/2019-Biodefense-Public-Report-508.pdf

Additionally, in fulfilment of their obligations under Article X, many States Parties conduct assistance programmes to support, through funding or otherwise, the development of other States Parties' capacities to deal with bio emergencies. Available offers can be consulted through the Article X Assistance and Cooperation Database accessible at https://bwc-articlex.unog.ch

Several international organisations and other partners also implement cooperation and assistance programmes that are directly relevant to BWC implementation in the area of bio emergencies. In particular:

- The WOAH can provide assistance to its Member States in reviewing and strengthening legislation in the veterinary domain relative to biological threats through its Veterinary Legislation Support Programme. Information on the VLSP programme can be found at https://www.oie.int/en/solidarity/options-for-targeted-support/veterinary-legislation-support/

- WHO provides support for national implementation of the International Health Regulations. Information can be found at https://www.who.int/health-topics/international-health-regulations.

- FAO, through its Animal Health Service and Emergency Prevention System (EMPRES), build resilience and capacities of countries to prevent and respond to disease threats including transboundary animal diseases, emerging infectious diseases and zoonoses. For more information, see http://www.fao.org/ag/againfo/programmes/en/empres/home.asp.

- The Global Health Security Agenda (GHSA) aims to strengthen both global and national capacities to prevent, detect, and respond to human and animal infectious disease threats whether naturally occurring or accidentally or deliberately spread; of particular relevance are its Action Packages seeking to advance in fulfilling the core capacity requirements for surveillance in accordance with the IHR and the WOAH standards and improve national, regional and global cooperation and collaboration in prevention, detection and control of zoonotic diseases. Information can be found at https://ghsagenda.org

MODULE VII – MEASURES TO PROMOTE INTERNATIONAL COOPERATION, ASSISTANCE AND EXCHANGE IN BIOLOGICAL SCIENCES AND TECHNOLOGY FOR PEACEFUL PURPOSES (MEASURES RELATED TO ARTICLE X)

Under Article X, States Parties "undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes." In addition, States Parties in a position to do so, shall "cooperate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes."

Article X also notes that the the BWC shall be implemented "in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international co-operation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention."

The Seventh and Eighth Review Conferences stressed the importance of the implementation of Article X and recalled that States Parties have a legal obligation to facilitate and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and not to hamper the economic and technological development of the States Parties.

To promote the full implementation of Article X, the Seventh Review Conference decided to establish a database to facilitate the exchange of requests for, and offers to provide, assistance and cooperation among States Parties. The database, which collects offers and requests of assistance and cooperation, is accessible at https://bwc-articlex.unog.ch. While all offers are public, requests can be only accessed by States Parties with a password.

States Parties are also encouraged to provide at least biannually appropriate information on how they implement Article X to the Implementation Support Unit (ISU), which collates such information and shares it with States Parties.[88] The information provided by States Parties illustrates the broad range of activities which may fit within the scope of Article X.

In order to further the implementation of Article X, consecutive Review Conferences have also recognised the need to effectively implement national measures and have urged States Parties to review their national regulations governing international exchanges and transfers in order to ensure their consistency with the objectives and provisions of all articles of the Convention.[89]

7.1 Scope of the national implementing measures

The Fourth Review Conference identified the following measures for the promotion of the fullest possible exchange of equipment, materials and scientific and technological information for the use of biological agents and toxins for peaceful purposes and of international cooperation in this field:

- Transfer and exchange of information concerning research programmes in the biosciences and greater cooperation in international public health and disease control;
- Transfer and exchange of information, materials and equipment among States on a systematic and long-term basis;
- Active promotion of contacts between scientists and technical personnel on a reciprocal basis, in relevant fields;

88 A compilation of the information submitted by States Parties was made available to the Eighth Review Conference through BWC/CONF.VIII/INF.4, dated 10 October 2016, and its Addendum 1, dated 20 October 2016, Addendum 2, dated 1 November 2016, and Addendum 3, dated 9 November 2016.

89 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article X, paragraph 70; BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article X, paragraph 60; and BWC/CONF.VI/6, Final Document of the Sixth Review Conference (2006), Part II, Article X, paragraph 52.

- Increased technical cooperation and assistance, including training programmes to developing countries in the use of biosciences and genetic engineering for peaceful purposes through active association with UN institutions;
- Facilitating the conclusion of bilateral, regional and multiregional agreements providing, on a mutually advantageous, equal and non-discriminatory basis, for their participation in the development and application of biotechnology;
- Encouraging the coordination of national and regional programmes and working out in an appropriate manner the ways and means of cooperation in this field;
- Cooperation in providing information on their national epidemiological surveillance and data reporting systems, and in providing assistance on a bilateral level and/or in conjunction with WHO, FAO and WOAH regarding epidemiological and epizootical surveillance, with a view to improvements in the identification and timely reporting of significant outbreaks of human and animal diseases;
- The promotion of programmes for the exchange and training of scientists and experts, and the exchange of scientific and technical information in the biological field between developed and developing countries.[90]

At the 2015 Meeting of States Parties, to further address a range of specific measures for the full and comprehensive implementation of Article X including facilitation of cooperation and assistance, States Parties also noted the value of:

> (a) avoiding imposing restrictions and/or limitations on transfers of scientific knowledge, technology, equipment and materials for purposes consistent with the objectives and provisions of the BWC;
>
> (b) assisting States Parties in the development of appropriate national systems of health care that can respond effectively to infectious disease outbreaks, including through contributing to the training of human resources, transfer of technologies to help improve national capacities for diagnosis, research, response, mitigation and recovery including means of protection, and promote academic and scientific exchange between national experts, and in this context welcomed initiatives that aim to promote and coordinate such assistance, upon request and with the consent of the State Parties;

90 See Final declaration of the Fourth Review Conference, Part II, in BWC/CONF.IV/9.

(c) the growing number of scientific publications and the need to promote wider access through reducing barriers, including the high costs of subscriptions;

(d) sharing relevant information about the opportunities and challenges resulting from scientific advances in the life sciences and in biotechnology, infectious disease outbreaks, healthcare, agriculture and industry, including through papers and expert presentations at BWC meetings;

(e) taking steps to facilitate and ensure that States Parties have full access to the benefits of advances in life sciences, for peaceful purposes including recent advances such as new technologies, the production or development of vaccines, biological production technologies, and equipment and training for appropriate levels of containment laboratories;

(f) facilitating the availability of cost-effective, affordable and quality-assured medicines, vaccines, diagnostics and related equipment and materials for peaceful purposes; and

(g) promoting collaborative research and development, including through exchange of scientists and providing training opportunities in advanced laboratories.

The Seventh and Eighth Review Conferences, while noting existing bilateral, regional and multilateral assistance, cooperation and partnerships, recognised, however, that there still remain challenges to be overcome in developing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes and that addressing such problems, challenges, needs and restrictions will help States Parties to build sufficient capacity for disease surveillance, detection, diagnosis and containment.[91]

91 See BWC/CONF.VIII/4, Final Document of the Eighth Review Conference (2016), Part II, Article X, paragraph 66; and BWC/CONF.VII/7, Final Document of the Seventh Review Conference (2011), Part II, Article X, paragraph 56.

Measures in furtherance of Article X could entail the following:

7.1.1 Reviewing national measures governing international exchanges and transfers

As outlined in Module IV, in order to implement Article III of the BWC, States Parties are required to take measures to control the transfers of biological agents, toxins, items and technologies identified as posing a risk to the BWC. In establishing such measures, States Parties should strike an appropriate balance between enabling transfers for peaceful biological applications and minimising the possibility of biological agents, toxins, items and technologies of relevance to the BWC being misused.

To ensure that the appropriate balance is maintained, States Parties should periodically review, and amend or adopt as necessary, their national measures governing international exchanges and transfers of BWC-relevant biological agents, toxins, items and technologies, including scientific and technological information for the use of such agents and toxins. Such review should ensure that adopted national measures, including control lists, do not impose undue restrictions and/or limitations on transfers of scientific knowledge, technology, equipment and materials for purposes consistent with the objectives and provisions of the Convention.

7.1.2 Entering into agreements or other forms of partnership

As illustrated by States Parties' regular submissions of information to the ISU in their national reports, measures taken by States Parties in furtherance of Article X are varied.[92]

To provide a more systematic and long-term basis to the partnerships concluded in furtherance of Article X and to facilitate international cooperation and assistance, States Parties could consider formalizing their cooperation through the conclusion of bilateral or multilateral agreements among States Parties and relevant international or regional organisations, or establishment of partnerships at the national or international level including public-private partnerships.

92 A compilation of the information submitted by States Parties was made available to the Eighth Review Conference through BWC/CONF.VIII/INF.4, dated 10 October 2016, and its Addendum 1, dated 20 October 2016, Addendum 2, dated 1 November 2016, and Addendum 3, dated 9 November 2016.

Such agreements may relate to:

- Exchange of information and sharing of scientific and technological knowledge, including on the national epidemiological surveillance and data reporting systems;
- Transfer and exchange of equipment, materials and scientific and technological information for the use of biological agents and toxins for peaceful purposes;
- Technical co-operation and assistance on a bilateral level and/or in conjunction with other States Parties or relevant organisations, including training programmes and sharing of experiences in the use of bio-sciences and genetic engineering for peaceful purposes or to support the development of effective response system;
- Participation in the development and application of biotechnology;
- Technology transfer.

Box 60 – Examples of international partnerships

- The African Coalition for Epidemic Research, Response and Training (ALERRT) is a multi-disciplinary consortium consisting of 21 partner organisations from 13 countries (nine African and four European). ALERRT aims to reduce the public health and socio-economic impact of disease outbreaks in sub-Saharan Africa by building a sustainable clinical and laboratory research preparedness and response network. For more information, see https://www.alerrt.global

- The European and Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 14 European and 16 African countries, supported by the European Union. EDCTP's mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies. EDCTP awards funding to collaborative clinical research projects conducted in sub-Saharan Africa on poverty-related infectious diseases, based on open, competitive and independently reviewed calls for proposals. For more information, see https://www.edctp.org

- The Global Health Security Agenda (GHSA) is a network of 69 countries, as well as international and non-government organisations, and private sector companies, working to secure global health security. As part of the Biosecurity and Biosafety Action Package, GHSA acts as a liaison between donors and recipients, pairing committed countries looking for support to donor countries seeking to direct resources towards effective capacity building. For more information, see https://ghsagenda.org

- The Global Health Security Initiative (GHSI) is an informal network of countries that came together shortly after the 11 September 2001 attacks in the United States, to ensure exchange and coordination of practices within the health sector in confronting new threats and risks to global health posed by terrorism. Delegations of the GHSI include Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States and the European Commission. The World Health Organization (WHO) serves as an observer. The mandate of the GHSI is to undertake concerted global action to strengthen public health preparedness and response to the threat of international CBRN terrorism. For more information, see at http://ghsi.ca

- The Global Partnership Against the Spread of Weapons and Materials of Mass Destruction is a G7-led, 31-member international initiative aimed at preventing the proliferation of CBRN weapons and related materials. Members of the Global Partnership coordinate and collaborate on an ongoing basis to develop and deliver projects and programmes to mitigate all manner of threats posed by CBRN weapons and related materials. For more information, see https://www.gpwmd.com. Document BWC/MSP/2018/WP.9, submitted by several Global Partnership member countries provides information on their international activities related to Article X.

- The *Red Iberoamericana Ministerial de Aprendizaje e Investigación en Salud* (Ibero-American Ministerial Network on Health Learning and Research – RIMAIS) aims to strengthen the capacities of Latin American Ministries of Health to develop the stewardship function for learning and research in public health, based on the socialisation of information and the know-how generated and disseminated via various regional initiatives. For more information, see http://www.rimais.net

7.1.3 Taking measures to address challenges in developing international cooperation, assistance and exchanges in biological sciences and technology for peaceful purposes

It has been recognised that there are challenges to the implementation of Article X, which may require measures at the legislative, regulatory or administrative levels. Such measures may need to be taken by both the States Parties providing assistance as well as the recipient States Parties and may relate to the following:

- Measures to support research and education in life sciences and related international cooperation activities, including through the provision of appropriate budgets;
- Conditions established by law and/or regulations to register and participate in academic or professional trainings or international exchange programmes of professionals, researchers and students;
- Visa procedures for foreign scientists or other professionals and students participating in research, training or educational programmes;
- Conditions of access to and availability of advanced technologies for application in peaceful uses;
- Patent law and its implications to provide access to essential medicines and vaccines;
- Intellectual property law and patent law and their implications on life science research, discoveries and innovations;
- Conditions for the dissemination of information on scientific and technological developments, including new research in areas relevant to the Convention, and for the provision of access to such information and relevant databases and networks;
- Biosafety and biosecurity measures in place in the recipient countries to protect and safeguard biological agents, toxins and related equipment and technologies, and prevent their misuse;
- Laws and policies on commercial activities and competition, as they would need to be robust, transparent and encourage foreign investments;
- Regulatory infrastructure and frameworks to promote trade and foreign direct investment;
- Customs procedures on the importation of medicines and vaccines, and measures setting customs tariffs and other fees on imported and exported goods.

Box 61 — Focus on the United States' experience

"3. Open access and online training courses

273. Many United States institutions support "open access" — the principle of making research results broadly available, free of charge. Open access databases promote collaboration and facilitate the spread of expertise throughout the globe, and diminish the costs associated with distributing scientific information and sharing results. In February 2013, the White House Office of Science and Technology Policy directed all federal departments and agencies to develop plans to make published results of federally funded research freely available to the public within one year of publication.

[...]

274. In addition, many U.S. colleges and universities have adopted open access policies requiring researchers to make their publications available free of charge. In some cases, these policies may apply only to graduate theses or faculty members in specific fields, or may allow researchers to opt in; some, however, apply broadly to all the research conducted at that institution. A growing number of major U.S. institutions are also making undergraduate and even some graduate courses freely available online. Yale University, the Massachusetts Institute of Technology, Stanford University, and the Johns Hopkins Bloomberg School of Public Health are among the U.S. universities providing free and open access to a variety of courses through their own websites or through online platforms such as Coursera or edX.

275. The Training Finder Real-time Affiliate Integrated Network (TRAIN) is funded in part by the Centers for Disease Control and Prevention (CDC) and managed by the Public Health Foundation (PHF), a private, non-profit organization. TRAIN is a web-based learning network for agencies and organizations that deliver, track, and share trainings for professionals who protect the public's health. The national TRAIN network is currently made up of 26 state health departments and three federal agencies (CDC, Medical Reserve Corps, and Veteran's Health Administration). Each has its own doorway into the national TRAIN network that allows these agencies o share courses with a growing learning system of more than one million registered learners. TRAIN offers health professionals access to courses on a wide array of public health topics in a variety of formats, including classroom training, webinars, and online self-study options.

Such online and distance learning opportunities enable the exchange of information between public health professionals and organizations and promote the development of the public health workforce."

Source: BWC/CONF.VIII/INF.4, dated 10 October 2016, "Implementation of Article X of the Convention, Background information document submitted by the Implementation Support Unit"

▼Second regional preparatory meeting for the Ninth Review Conference of the BWC, held in Panama, August 2022. Photo credit: BWC ISU.

ANNEX 1 – GLOSSARY

The following definitions are provided to explain some of the key terms used in this Guide. They have not, however, been adopted, endorsed, approved, or otherwise acted upon by BWC States Parties or any organ of the United Nations, and should not be viewed as official definitions of these terms.

1925 Geneva Protocol

The Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare, commonly known as the 1925 Geneva Protocol, prohibits the use of chemical and biological weapons in war. The Protocol was negotiated and signed at a conference held in Geneva under the auspices of the League of Nations from 4 May to 17 June 1925 and entered into force on 8 February 1928. The text of the Protocol is available at https://www.un.org/disarmament/wmd/bio/1925-geneva-protocol/

Biological agent

Any microbial or other biological agent, naturally or artificially created or altered, as well as its components, whatever its origin or method of production, that may cause harm to humans, animals or plants.

Biological laboratory

A facility within which microorganisms, their components or their derivatives are collected, handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc.) for human, veterinary and agricultural purposes.

(Source: *Biorisk management: Laboratory Biosecurity Guidance*, WHO, 2006)

Biological Weapon

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

Biorisk

The probability or chance that a particular adverse event (accidental infection or unauthorised access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.

(Source: *Biorisk management: Laboratory Biosecurity Guidance*, WHO, 2006)

Biorisk management

The analysis of ways and development of strategies to minimize the likelihood of the occurrence of biorisks. The management of biorisk places responsibility on the facility and its manager (director) to demonstrate that appropriate and valid biorisk reduction (minimization) procedures have been established and are implemented. A biorisk management committee should be established to assist the facility director in identifying, developing and reaching biorisk management goals.

(Source: *Biorisk management: Laboratory Biosecurity Guidance*, WHO, 2006)

Biosafety

Principles, technologies, practices and measures implemented to prevent accidental release of, or unintentional exposure to, biological agents and toxins.

(Source: BWC/MSP/2008/5, dated 12 December 2008, Report of the Meeting of States Parties, paragraph 20)

Biosecurity

Protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorized access to, retention or transfer of such material.

(Source: BWC/MSP/2008/5, dated 12 December 2008, Report of the Meeting of States Parties, paragraph 20)

Biotechnology

The application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

(Source: Second OECD Ad Hoc Meeting on Biotechnology Statistics, OECD, May 2001)

Customs Transit

Customs procedures under which goods are transported under Customs control from one Customs office to another. (Source: Glossary of International Customs Terms, WCO, 2018).

Dual-use

Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also to harmful misuse and peaceful activities.

(Source: Biorisk Management: Laboratory Biosecurity Guidance, WHO, 2006)

Exportation

The act of taking out or causing to be taken out any goods from the Customs territory.

(Source: Glossary of International Customs Terms, WCO, 2018)

Implementation Support Unit (ISU)

The Implementation Support Unit of three fixed-term staff members was established within the Geneva Branch of the United Nations Office for Disarmament Affairs by the Sixth Review Conference in 2006. The ISU's mandate was renewed at the Seventh and Eighth Review Conferences in 2011 and 2016 respectively. The ISU is mandated to provide:

- Administrative support and assistance;
- National implementation support and assistance;
- Support and assistance for Confidence-Building Measures;

- Support and assistance for obtaining universality;
- Administration of the database for assistance requests and offers and facilitation of associated exchanges of information; and
- Support for States Parties' efforts to implement the decisions and recommendations of the review conferences.

Importation

The act of bringing or causing any goods to be brought into a Customs territory.

(Source: Glossary of International Customs Terms, WCO, 2018)

Intersessional programme

Programme of annual BWC meetings between Review Conferences held since 2003 with a mandate to discuss, and promote common understandings and effective action on specific topics to strengthen the implementation of the Convention. There have been four intersessional programmes thus far: 2003-2005; 2007-2010; 2012-2015; and 2018-2020.

Living organism

Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

(Source: Cartagena Protocol on Biosafety)

Life sciences

All sciences that deal with living organisms, including human beings, animals and plants. It is a broad field that encompasses biology, biotechnology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and techniques.

(Source: Working paper *Life science research: opportunities and risks for public health: mapping the issues*, WHO, 2005)

Meetings of Experts

Meetings held on an annual basis in preparation of the annual Meeting of States Parties to the BWC. The Meetings of Experts consider agreed technical topics and prepare factual reports reflecting their deliberations, including possible outcomes, for consideration by the subsequent Meeting of States Parties.

Meeting of States Parties

Meeting of all States Parties to the BWC held on an annual basis to discuss, and promote common understanding and effective action on the topics identified by the Review Conference. As per the decision of the 2017 Meeting of States Parties[93], the Meetings of States Parties have also been responsible for managing the intersessional programme, including taking necessary measures with respect to budgetary and financial matters by consensus with a view to ensuring the proper implementation of the intersessional programme.

National Implementation Measures

Legislative, regulatory, administrative, judicial and other measures taken by States Parties to give effect domestically to the provisions of the BWC, including to enforce the prohibitions set forth in the BWC and enable States Parties to meet their international obligations.

Pathogen

A biological agent capable of causing disease in humans, animals or plants.

(Source: *Laboratory Biosafety Manual*, Fourth Edition, WHO, 2020)

Peaceful purposes

Peaceful purposes relate to any prophylactic, protective or other purposes not intended to cause harm to humans, animals or plants.

93 See BWC/MSP/2017/6, Report of the Meeting of States Parties, dated 19 December 2017, paragraph 19 (f).

Review Conference

The Conferences of BWC States Parties, normally held every five years, which, in accordance with Article XII of the BWC, review its operation with a view to assuring that the purposes of its preamble and its provisions are being realised. Such conferences also take into account any new scientific and technological developments relevant to the Convention.

Review Conference Final Document

The substantive and procedural output of BWC Review Conferences is recorded in the Final Document. Traditionally, the Final Document is made up of a procedural report and a Final Declaration, where States Parties recommit themselves to the aims and objectives of the BWC, and which reflects understandings and agreements relating to each Article of the BWC. The Final Document of the Sixth, Seventh and Eighth Review Conferences also included a section on Decisions and Recommendations including, amongst other things, the mandate for the Intersessional Programmes and the Implementation Support Unit.

Signatory State

A State which has signed an international treaty or convention but has not yet ratified it.

State Party

A State in respect of which an international treaty or convention has entered into force, in the conditions set forth in the treaty or convention normally requiring the deposit of an instrument of ratification, acceptance, approval or accession.

Toxin

Includes any toxin, both proteinaceous and non-proteinaceous, of a microbial, animal or vegetable nature and its synthetically produced analogues.

Transhipment

Customs procedure under which goods are transferred under Customs control from the importing means of transport to the exporting means of transport within the area of one Customs office which is the office of both importation and exportation.
(Source: Glossary of International Customs Terms, WCO, 2018)

United Nations Office for Disarmament Affairs (UNODA)

The Office in the United Nations Secretariat dedicated to addressing disarmament and non-proliferation issues. Prior to the creation of the BWC Implementation Support Unit in 2006, this Office provided support for the BWC. The Implementation Support Unit is housed within the Geneva Branch of UNODA.

United Nations Security Council resolution 1540 (2004)

A Security Council resolution, unanimously adopted on 28 April 2004 under Chapter VII of the United Nations Charter, requiring States, *inter alia*, to:

i. refrain from supporting by any means non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems;

ii. adopt and enforce appropriate effective laws prohibiting activities involving the proliferation of such weapons and their means of delivery to non-State actors, in particular for terrorist purposes, as well any attempts to engage in such activities, assist or finance them; and

iii. implement and enforce appropriate controls over related materials in order to account for and secure items in production, use, storage or transport; physically protect such materials; detect, deter, prevent and combat the illicit trafficking and brokering through effective border controls and law enforcement efforts; control the export, transit, trans-shipment and re-export and the provision of funds and services related to such export and trans-shipment that would contribute to proliferation; penalize violations.

ANNEX 2 – INDICATIVE LIST OF BWC IMPLEMENTING MEASURE

Article I, read in combination with Article IV and as supplemented by understandings reached by States Parties	Adopt penal measures to:
	- Establish offences and penalties for the violation of the prohibition to develop, produce, stockpile, or otherwise acquire, retain or use, in any way and under any circumstances: • Microbial or other biological agents, or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, • Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.
	- Define the scope of the above offences, by providing definitions of terms or otherwise ensure that such prohibition applies to: • All naturally or artificially created or altered microbial or other biological agents, or toxins, as well as their components, including toxins (both proteinaceous and non-proteinaceous) of a microbial, animal or vegetable nature and their synthetically produced analogues, regardless of their origin and method of production and whether they affect humans, animals or plants, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; • Scientific and technological developments in the life sciences and in other fields of science relevant to the BWC, inter alia, in the fields of microbiology, genetic engineering, biotechnology, molecular biology and any applications resulting from genome studies, where intended to be used for purposes inconsistent with the objectives and the provisions of the BWC.

	- Establish offences and penalties for assistance, encouragement, inducement in any way to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention.
	- Establish jurisdiction over above offences where committed within the State Party's territory or anywhere under its jurisdiction or control.
	- Establish jurisdiction over above offences where committed anywhere by legal or natural persons possessing the State's nationality.
	- Grant investigation, enforcement and prosecution powers to relevant authorities.
	Establish procedures to ensure coordination among relevant national authorities, and provide the legal framework for international cooperation and mutual legal assistance in investigations, prosecutions and judicial proceedings with other States Parties.
	Take complementary measures as necessary to promote awareness of the BWC and the national implementing measures, and the need to report activities that could constitute a BWC-related offence.
Article II, as supplemented by understandings reached by States Parties	**Establish procedures** to:
	- Ensure the destruction or diversion to peaceful purposes of all agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, which are in its possession or under its jurisdiction or control.
	- Adopt safety and security provisions to protect populations and the environment, including animals and plants, when carrying out the destruction and/or diversion of prohibited agents, toxins, weapons, equipment or means of delivery, including conditions of storage.

	- Record relevant information on prohibited agents, toxins, weapons, equipment or means of delivery and their destruction or diversion, including for the purpose of the CBM submission (Form F).
Article III, as supplemented by understandings reached by States Parties	**Adopt penal measures** to:
	- Establish offences and penalties for the violation of the prohibition to transfer to any recipient whatsoever, directly or indirectly, any of the microbial or other biological agents, or toxins, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.
	- Establish offences and penalties for assistance, encouragement or inducement in any way to commit above offence.
	- Establish jurisdiction over above offence where committed within the State Party's territory or anywhere under its jurisdiction or control.
	- Establish jurisdiction over above offence where committed anywhere by legal or natural persons possessing the State's nationality.
	- Grant investigation, enforcement and prosecution powers to relevant authorities.
	Establish procedures to ensure coordination among relevant national authorities, and provide the legal framework for international cooperation and mutual legal assistance in investigations, prosecutions and judicial proceedings with other States Parties.

	Adopt legislative and/or regulatory measures to establish a control regime over international (cross-border) and internal (within the country) transfers of BWC-relevant biological agents, toxins, weapons, equipment, means of delivery and technologies, including:
	- Specify the activities and biological agents, toxins, weapons, equipment, means of delivery and technologies, subject to control.
	- Establish a national authorisation regime over the controlled activities, including end-use or end-user controls, licensing exemptions and simplified control procedure over transfers of listed agents, toxins, items or technologies where intended for humanitarian or emergency assistance.
	- Provide for a catch-all clause, enabling controls over non-listed biological agents, toxins, items or technologies in case of suspected violation of the penal measures adopted in furtherance of Article I of the BWC.
	- Establish offences and penalties for engagement in a cross-border or internal transfer of listed biological agents, toxins, items or technologies without the required license or registration or in violation of the related requirements or conditions of the license, except where exempted.
	- Designate or establish the licensing or registration authority and set forth its functions and powers.
	- Grant inspection and enforcement powers to relevant authorities.
	- Adopt physical protection measures to protect and safeguard biological agents, toxins, and BWC-relevant items through measures to control access to and handling of such agents, toxins, and items where stored at borders or during transportation.
	- Provide for appropriate information sharing and coordination procedures amongst all relevant authorities, to address cases of suspicious prohibited activities.

	Take complementary measures as necessary to assist front-line officers to conduct effective controls and raise awareness of all relevant stakeholders.
	Adopt regulatory and/or administrative measures to designate a national point of contact and establish institutional arrangements, as appropriate, to administer the implementation of the BWC.
Article IV, as supplemented by understandings reached by States Parties	**Adopt penal measures** (please refer to Article I above)
	Adopt legislative and regulatory measures on biosafety and biosecurity, including:
	- Establish a list of biological agents and toxins subject to controls
	- Establish a national control regime over high-risk biological agents and toxins, including: • Subject to licensing or registration the conduct of activities involving listed biological agents and toxins, such as the development, production, use, stockpiling, acquisition or retention. • Provide for exemptions from the licensing or registration requirement in specific cases. • Require periodic reporting. - Require compliance by the laboratories or facilities at which controlled activities are conducted with biosafety and biosecurity standards, including: • Maintaining appropriate physical protection measures. • Establishing a biosecurity plan. • Ensuring the personnel has appropriate biosafety and biosecurity training. • Designating a biosafety/biosecurity officer. • Requiring security clearance of personnel working with listed biological agents and toxins.
	- Establish control measures over the transportation of high-risk agents and toxins.
	- Establish offences and penalties for engagement in controlled activities without complying with the requirements established by the implementing measures or as part of the licence conditions.

	- Designate the relevant authorities, including the licensing authority(ies), and grant them necessary powers to conduct compliance verifications.
	- Establish measures to account for BWC-relevant biological agents or toxins, by: • Establishing a national inventory of such agents and toxins and the laboratories and facilities where they are kept. • Introducing a mandatory system for the notification of the loss, theft or release of BWC-relevant biological agents and toxins. • Enabling the competent authorities to control the internal movements of BWC-relevant agents and toxins.
	- Take measures to address the risks posed by dual-use research of concern.
	Take complementary measures, including to:
	- Support and encourage the voluntary development, adoption and promulgation of codes of conduct for scientists and other relevant professionals and development of best practices.
	- Promote amongst relevant professionals in the private or public sectors, including those working in the biological sciences, awareness of the obligations under the BWC and national law, and ensure the inclusion in medical, scientific and military educational materials and programmes of information on the BWC and the 1925 Geneva Protocol.
	- Promote training and education programmes for those granted access to BWC-relevant biological agents and toxins and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as of the obligations.
	Take measures to establish an effective national infrastructure for human, animal and plant disease surveillance and detection.

Article VII, as supplemented by understandings reached by States Parties	Take measures to establish an appropriate organisational structure to coordinate response and investigation of unusual disease outbreaks and biological incidents.
	Develop national emergency management plans.
	Take measures to enable and/or facilitate the provision or receipt of assistance and protection to any State Party which so requests under Article VII, including by:
	- Concluding agreements or arrangements as required to enable timely emergency assistance by States Parties where required.
	- Taking measures to address identified legal and regulatory challenges to the provision or receipt of such assistance.
	Take measures to facilitate investigations, including by:
	- Establishing procedures for sampling and analysis. - Establishing procedures to ensure appropriate coordination and communication between health and law enforcement authorities.
	- Concluding mutual legal assistance arrangements with other States Parties.
Article VIII, as supplemented by understandings reached by States Parties	Take measures to:
	- Accede to the 1925 Geneva Protocol;
	- Where applicable, withdraw reservations to the 1925 Geneva Protocol and/or conduct national reviews to look into this matter with a view to expediting withdrawal of such reservations.

Article X, as supplemented by understandings reached by States Parties	**Review the national measures governing international exchanges and transfers** in order to ensure their consistency with the objectives and provisions of all the articles of the Convention.
	Enter into bilateral or multilateral agreements with other States Parties and relevant international or regional organisations, and/or establish partnerships at national or international level including public-private partnerships.
	Take measures to address challenges in developing international cooperation, assistance and exchanges in biological sciences and technology for peaceful purposes.

ANNEX 3 – ILLUSTRATIVE RESOURCES FOR NATIONAL IMPLEMENTATION

Resources for the conduct of a self-assessment and gap analysis

States Parties engaging in the conduct of a self-assessment and gap analysis could find it useful to refer to the materials and tools listed below, which – though not all specifically or exclusively designed for BWC implementation – may, however, be relevant. Additional resources of specific relevance for the conduct of a risk assessment, or a self-assessment and gap analysis in the area of biosafety and biosecurity or bioemegency preparedness and response are provided in dedicated boxes in Module V (Boxes 50 and 52) and Module VI (Box 59).

The BWC Implementation Review Reporting Form, developed by Canada, Chile, Ghana, Mexico and the United States

Canada, Chile, Ghana, Mexico and the United States collaborated in a BWC Implementation Review initiative, for the purposes of improving national implementation of the BWC through the sharing of information and experiences, increasing transparency, and providing good practices that other States Parties could consider in their own efforts. The five States Parties developed a national reporting form which was the basis for their exchange of information. The form contains a list of questions on national measures to address specific aspects of implementation, which States Parties may find useful to use for the purpose of the self-assessment and gap analysis of their national framework. This Form can be found in the Appendix to the working paper BWC/CONF.VIII/WP.22 submitted by the five States Parties to the Eighth Review Conference.

Questionnaire for evaluating the facilities carrying out contained activities with biological agents, developed by Chile, Colombia, Mexico and Spain

At the 2014 Meeting of Experts, Chile, Colombia, Mexico and Spain made available, in English and Spanish, a questionnaire for evaluating facilities carrying out contained activities with biological agents. This questionnaire, contained in BWC/MSP/2014/MX/WP.6, was developed to assess the suitability regarding the degree of biological containment and confinement measures applied to different biological agents in different laboratories, so as

to gain a better understanding of the processes and standards applied while establishing the degree of risk inherent to handling such biological agents, and acquire relevant information on the facilities dealing with biological agents on a national level.

Online courses developed by the Public Health Agency of Canada (PHAC)

The PHAC has developed *An Analytical Approach for the Development of a National Biosafety and Biosecurity System*, a tool to strengthen global biosafety and biosecurity. The Analytical Approach is a methodology that can be used by regional, national or local authorities in the development or modernisation, and implementation of national policies and oversight frameworks for biosafety and biosecurity. The Analytical Approach is structured around modules. The first of these modules explains how to identify the current state of biosafety/biosecurity in a country or region, including how to identify issues within a biosafety/biosecurity system, the key aspects of risk assessment and prioritization and the key aspects of root cause analysis. The tool is available for use as both a downloadable manual and an online e-learning course in English and French by creating a free account at https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/analytical-approach.html.

The PHAC's training portal also includes many other free courses, amongst which the *Insider and Outsider Threat course*. This course describes the motives, tactics, and indicators of insider and outsider threats. It proposes mitigation strategies which aim to reduce the occurrence of biosecurity events associated with insider and outsider threats. See https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=54

Guidance by the Danish Centre for Biosecurity and Biopreparedness (CBB)

Guidance on how to conduct a gap analysis for the purpose of assessing the existing state of biosecurity and identify biosecurity strengths and weaknesses can be found in the publication by the Danish Centre for Biosecurity and Biopreparedness (CBB), "An efficient and practical approach to Biosecurity", available at https://biosecuritycentral.org/resource/core-guidance-and-recommendations/efficient-and-practical-approach-to-biosecurity/.

The Biosecurity Self-Scan Toolkit, Biosecurity Vulnerability Scan and Dual-Use Quickscan by the Dutch Biosecurity Office

The Dutch Biosecurity Office has developed two toolkits that can be helpful to provide an indication of the current level of biosecurity. These toolkits are intended for organisations that work with biological agents or come into regular contact with them. The Toolkit and the Vulnerability Scan are accessible in English from https://www.bureaubiosecurity.nl/en/node/541 and in Dutch from https://www.bureaubiosecurity.nl/pijlers/biosecurity-bewustwording. The Biosecurity Self-Scan Toolkit is also available in French from https://outilevaluationbiosecurite.nl/home. The Dutch Biosecurity Office has also developed a Dual-Use Quickscan, available at https://dualusequickscan.nl/. The Dual-Use Quickscan aims at identifying potential dual-use aspects in research and at contributing to stimulate dual-use awareness among researchers.

The Self-Assessment Framework by the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences is developing a Self-Assessment Framework, intended to provide a measure of the organisational culture of biosafety, biosecurity, and responsible conduct to aid in the process of enhancing such culture at the local level through baseline and periodic assessments. The January 2020 Working Draft is available at https://absa.org/wp-content/uploads/2020/02/Culture_of_Biosafety-Biosecurity_Self-Assessment_Framework.pdf. The accompanying Excel template is available at https://absa.org/wp-content/uploads/2020/02/Culture_of_Biosafety-Biosecurity_Self-Assessment_Framework-Template.xlsx. The French version is available on request.

1540 Matrices of Member States

The 1540 Matrix has functioned as the primary method used by the 1540 Committee to organise information about implementation of Security Council resolution 1540 (2004) by Member States. The Matrix has fields representing the requirements of the resolution alongside the measures that States have taken in respect of these requirements. A Matrix for each Member State has been prepared by the Group of Experts and subsequently approved by the Committee. The information in the matrices originates primarily from national reports provided by Member States to the 1540 Committee and is complemented by official government information, including that made available to intergovernmental organisations.

The 1540 Matrices are available at https://www.un.org/en/sc/1540/national-implementation/1540-matrices/committee-approved-matrices.shtml

WHO Joint External Evaluations

A Joint External Evaluation (JEE) is a voluntary, collaborative, multisectoral process to assess country capacities to prevent, detect and rapidly respond to public health risks whether occurring naturally or due to deliberate or accidental events. The JEE tool and process are key components of the IHR Monitoring and Evaluation Framework and have been developed and implemented in full concordance and collaboration with related efforts such as the Global Health Security Agenda and the WOAH's Performance of Veterinary Services Pathway. The JEE helps countries identify the most critical gaps within their human and animal health systems in order to prioritize opportunities for enhanced preparedness and response. To date, JEEs have been conducted in more than 100 countries. For more information on the JEE tool and its process, please refer to https://www.who.int/publications/i/item/9789240051980. States may also access to the JEE mission reports, showing the results of the evaluations conducted, from https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/joint-external-evaluations.

IHR (2005): Toolkit for implementation in national legislation: Questions and answers, legislative reference and assessment tool and examples of national legislation, WHO 2009

This Toolkit provides guidance on the implementation of the IHR (2005) in national legislation. Section II.3 of the Toolkit features a legislative reference and assessment tool to support assessment by States of their relevant existing legislation against all of the rights and obligations they have under the IHR, as well as consideration of potential follow-up actions. The Toolkit is available in English from https://www.who.int/docs/default-source/documents/emergencies/ihr-toolkit-for-implementation-in-national-legislation.pdf?sfvrsn=60aea14d_1.

Biological Threat Agents Information

Background information on a number of relevant biological threat agents often mentioned in discussions pertaining to biocrimes, bioterrorism, biosafety and public health can be found on the Virtual Biosecurity Center's website at https://www.virtualbiosecuritycenter.org/education-center/biological-threat-agents-information-2/.

Resources for legislative drafters

Model implementing measures

African Union Model Law

A Model Law on Weapons of Mass Destruction Disarmament and Non-Proliferation is being developed by the African Union Commission.

CARICOM Model Law

CARICOM has developed a Model Act to implement UN Security Council resolution 1540 and treaty obligations relating to the prevention, of proliferation of nuclear, chemical and biological weapons (Strategic Trade Control Act).

VERTIC legislative assistance tools

All VERTIC assistance tools are freely available from its website at https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-tools/

VERTIC: Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 (2004)

The Sample Act was developed by VERTIC to assist countries in drafting legislation to implement the BWC and the biological weapons-related provisions of resolution 1540. It is a tool which legislative drafters may freely draw on, while taking into consideration their country's legal framework, level of biotechnological development and other national circumstances. Available in Arabic, Azeri, Bahasa Indonesian, English, French, Georgian, Portuguese, Russian, and Spanish; civil law versions of the Act are also available in French and Spanish. The Sample Act is under revision at the time of writing.

ICRC and VERTIC: Model Law – The Biological and Toxin Weapons Crimes Act

The ICRC-VERTIC Model Law is intended for States with a common law legal tradition, although States with different legal traditions may find some of the provisions relevant. It is also intended for States with little or no biotechnology industry. It provides for, but does not formulate, internal regulations nor does

it cover separate administrative measures that arise from implementation of the BWC and resolution 1540. The main emphasis in the Model Law is placed on the prohibition, backed up by penal sanctions, of the weapons and acts defined in the BWC and in the 1925 Geneva Protocol. Available in Arabic, English and Spanish.

VERTIC: Regulatory Guidelines for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 (2004)

VERTIC developed the Regulatory Guidelines as guidance for States when they are engaged in the process of preparing any regulatory and administrative measures that may be necessary to supplement their primary legislation for national implementation of the BWC, as well as the biological weapons-related provisions of resolution 1540. They are not a set of model regulations, but rather suggestions, tips and links to examples of proven practice, which States may choose to review and utilize, taking into account their own legal framework and traditions, level of biotechnological development and other national circumstances. Available in Arabic, English, French, Georgian, Portuguese, Russian and Spanish. The Regulatory Guidelines are under revision at the time of writing.

VERTIC Legislation Drafting Assistant tool

The VERTIC's Legislation Drafting Assistant is intended to support States to develop a tailored draft bill for the implementation of the BWC and related provisions of UN Security Council resolution 1540 (2004). This tool is accessible from https://www.vertic.org/programmes/biological-weapons-and-materials/legislation-drafting-assistant/.

VERTIC Legislation Survey Template for the implementation of the BWC

In order to assist States to comprehensively analyse their legislation, VERTIC has developed a so-called "legislation survey" template for the BWC. In addition, a "survey overview" template provides a place to summarise the survey's main findings and formulate recommendations to strengthen legislation. The BWC legislation survey template is available in English and French, survey templates in Arabic, Russian and Spanish will be published in the near future. For more information see https://www.vertic.org/programmes/nim/biological-weapons-and-materials/legislative-analysis-tool/.

Legislation databases

Legislation relevant to the BWC

VERTIC maintains a BWC Legislation Database with over 1,500 laws and regulations located through open sources by VERTIC staff. The database contains examples of legislation covering criminal provisions, biosafety and biosecurity measures, export control measures and enforcement. Available at https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/.

Legislation relevant to United Nations Security Council resolution 1540 (2004)

The 1540 matrices reflecting the measures that UN Member States have taken for the fulfilment of their obligations under resolution 1540 are available at https://www.un.org/en/sc/1540/national-implementation/1540-matrices/committee-approved-matrices.shtml. The website also contains national reports which detail legislation and enforcement measures taken to enact in furtherance of the obligations under resolution 1540. Available at http://www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

Legislation relevant to counter-terrorism

A database of legislation relevant to counter-terrorism is available on the UNODC website.

Legislation relevant to the Chemical Weapons Convention (CWC)

A compendium of legislation enacted by States Parties to the Chemical Weapons Convention is available on the OPCW website at https://www.opcw.org/resources/national-implementation/legislation-compendium.

Legislation relevant to the Cartagena Protocol

National laws and regulations relevant to the implementation of the Cartagena Protocol on Biosafety and to the Convention on Biodiversity can be searched from the Biosafety Clearing House portal at https://bch.cbd.int/database/laws/.

Legislation relevant to disaster management

The IFRC has developed legislative assistance tools to assist States in developing legal frameworks in the area of international disaster preparedness and response. These tools are available at https://www.ifrc.org/en/what-we-do/disaster-law/about-disaster-law/international-disaster-response-laws-rules-and-principles/. These include a database referencing laws, regulations and policies on disaster management. This database is available at: www.ifrc.org/en/publications-and-reports/idrl-database/

Other IFRC tools include:

- Guidelines for the domestic facilitation and regulation of international disaster relief and initial recovery assistance. Available at https://disasterlaw.ifrc.org/idrlguidelines.

- Model Act for the Facilitation and Regulation of International Disaster Relief and Initial Recovery Assistance. Available at https://disasterlaw.ifrc.org/media/1772.

- Model Emergency Decree for the Facilitation and Regulation for International Disaster Relief and Initial Recovery Assistance. Available at: https://disasterlaw.ifrc.org/media/1324.

Resources for parliamentarians

Parliamentarians for Global Action (PGA): Handbook to Promote International Legislative Frameworks Addressing the Threats Posed by Weapons of Mass Destruction & Promotion of Bio-Risk Management Best Practices

This Handbook is available in Arabic and English at https://www.pgaction.org/resources-for-parliamentarians.html#bwc.

Inter-Parliamentary Union (IPU): Seminar Proceedings

- Proceedings of the Regional Seminar organised by IPU and the New Zealand House of Representatives, "Engaging parliaments of the Pacific region in the implementation of UN Security Council resolution 1540 (2004), 18–20 September 2019, New Zealand Parliament (Wellington)", is available at https://www.ipu.org/resources/publications/reports/2020-01/engaging-parliaments-pacific-region-in-implementation-un-security-council-resolution-1540/.
- Proceedings of the Regional Seminar organised by IPU and the Parliament of Côte d'Ivoire, "Effective implementation of Resolution 1540 in Africa: opportunities for parliaments, Regional seminar for African parliaments Abidjan, 22-23 February 2016", is availale at https://www.ipu.org/resources/publications/reference/2016-07/effective-implementation-resolution-1540-in-africa-opportunities-parliaments/

Parliamentarians for Nuclear Non-proliferation and Disarmament (PNND): Assuring our Common Future: A guide to parliamentary action in support of disarmament for security and sustainable development

This handbook, produced by partner organisations (Geneva Centre for Security Policy, IPU, PGA, PNND, Parliamentary Forum on Small Arms and Light Weapons, World Future Council), with support and input from UNODA, is available at: https://disarmamenthandbook.org

Resources on biosafety and biosecurity

Canada: An Analytical Approach for the Development of a National Biosafety and Biosecurity System

For the full description, see above. The tool is available for use as both a downloadable manual and an online e-learning course in English and French by creating a free account at https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/analytical-approach.html

Denmark: An efficient and practical approach to biosecurity

This publication was created by the Danish Centre for Biosecurity and Biopreparedness (CBB) as an aid to those States that are still in the process of establishing national biosecurity systems. The aim of the book is to draw upon Denmark's experiences with biosecurity to suggest an efficient and practical model that other countries can use—in whole or in part—as a blueprint for establishing or improving their own biosecurity systems. This publication is available in both English and Russian. Further material is also available from https://www.biosecurity.dk/resources.

Resources by the World Health Organization (WHO)

WHO Guidance on Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories: A Stepwise Approach (2020)

This Guidance document aims to inform and support national legislative and executive authorities, policymakers and regulators in creating, refining and implementing a regulatory framework for ensuring the highest standards of laboratory biosafety and biosecurity. This document provides recommendations and incudes a high-level review of existing biosafety and biosecurity regulations in selected WHO Member States, as well as a questionnaire tool to assist users conduct a comprehensive initial situational analysis of existing biosafety and biosecurity controls in biomedical laboratories. Available at https://apps.who.int/iris/handle/10665/332244.

Laboratory Biosafety Manual (2020)

The Manual provides a risk-based, technology-neutral and cost-effective approach to biosafety, with guidance on the feasibility of laboratory operations even in resource-limited settings. The Manual also provides an overview of biosecurity. This publication provides guidance specifically for those who work with biological agents or in facilities where personnel may be exposed to potentially infectious substances that present a hazard to human health. It can be used to drive a safety culture for every day laboratory practices and procedures. It will also be of value to those building or renovating laboratory facilities and to countries developing or implementing biosafety programmes and national-level frameworks for biosafety oversight. Available from https://www.who.int/publications/i/item/9789240011311.

Biorisk Management: Laboratory Biosecurity Guidance (2006)

The WHO Biorisk management: Laboratory biosecurity guidance (2006) provides detailed guidance on biosecurity within a biological laboratory and addresses its basic principles and best practices. Available in English and Japanese from https://apps.who.int/iris/handle/10665/69390.

Responsible Life Sciences Research for Global Health Security — A Guidance Document (2010)

The purpose of this Guidance is to inform States about the risks posed by accidents or the potential deliberate misuse of life sciences research and to propose measures to minimize these risks within the context of promoting and harnessing the power of the life sciences to improve health for all people. Available from https://apps.who.int/iris/bitstream/handle/10665/70507/WHO_HSE_GAR_BDP_2010.2_eng.pdf?sequence=1&isAllowed=y.

Guidance on Regulations for the Transport of Infectious Substances 2019–2020

This publication provides practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally. It provides information for identifying, classifying, marking, labelling, packaging, documenting and refrigerating infectious substances for transportation and ensuring their safe delivery. Available in English, French, Spanish and Farsi from https://www.who.int/publications/i/item/WHO-WHE-CPI-2019.20

Working paper: Life science research: opportunities and risks for public health: mapping the issues, WHO, 2005

This working paper reviews amongst others selected life science research and development, related techniques and their associated risks, as well as Risks of misuse of life science research and development. Available at https://apps.who.int/iris/bitstream/handle/10665/69142/WHO_CDS_CSR_LYO_2005.20.pdf?sequence=1&isAllowed=y.

Additional WHO resources on laboratory biorisk management, including training materials and tools and disease specific recommendations are available from https://www.who.int/publications/i/item/9789240011311.

Resources by the Food and Agriculture Organization of the United Nations (FAO)

Biosecurity Toolkit (2008)

This toolkit provides practical guidance and support to develop and implement national biosecurity frameworks at the country level. It presents the benefits of a harmonised and integrated approach to biosecurity and illustrates the experiences of countries, which have adopted such an approach. The toolkit comprises three parts. The first part provides a broad introduction to biosecurity and outlines the contemporary context for development and implementation of a harmonised and integrated biosecurity approach across all sectors. The second part provides guidance on how to assess dimensions of biosecurity capacity across all sectors and sector organisations in accordance with the requirements of an integrated biosecurity approach. The third part of the toolkit presents a generic framework to structure and guide the application of risk analysis principles in biosecurity. Available at http://www.fao.org/3/a1140e/a1140e00.htm.

Resources by the Organisation for Economic Cooperation and Development (OECD)

OECD Best Practice Guidelines on Biosecurity for Biological Resources Centres

The OECD Best Practice Guidelines on Biosecurity for Biological Resources Centres (BRCs) were endorsed by OECD member countries in March 2007. These Guidelines describe the methods and protocols for secure maintenance and provision of biological materials. Available in English and Spanish at http://www.oecd.org/sti/emerging-tech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm.

Resources by the Stockholm International Peace Research Institute (SIPRI)

Handbook of Applied Biosecurity for Life Science Laboratories, by Peter Clevestig (2009)

This handbook provides guidance for personnel who work with infectious pathogens and toxins that may affect the health of humans, animals and plants. It aims to engage scientists, laboratory employees and students in laboratory biosecurity, and to provide practical advice that will ensure the secure handling and storage of biological materials. Available at https://www.sipri.org/publications/2009/handbook-applied-biosecurity-life-science-laboratories.

Resources by the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

The Guide provides information about training and educational resources related to the culture of biosafety, biosecurity, and responsible conduct in the life sciences. The guide highlights courses and repositories of training/educational resources, including professional certification and competencies on biosafety/biosecurity; select conferences or events where the culture of biosafety and biosecurity was addressed; resources on dual use research of concern, ethics, and codes of conduct; and relevant publications. This Guide is available at https://absa.org/wp-content/uploads/2019/04/CULTURE_TRAINING_CATALOGUE.pdf.

The Biosecurity Resource Toolbox

The Biosecurity Resource Toolbox was created as part of EU project "The preparation of a biosecurity toolbox to strengthen European Biosecurity" with financial support from the European Commission. The resources available in the toolbox include interactive tools to mitigate insider threats at strategic and sensitive industries, checklists for the identification of vulnerabilities for strategic industries that house CBRN and dual use items, and documents related to legislation, guidelines, and best practices concerning biosecurity.

The toolbox is categorized into six themes: Legislation, policy & codes; Self-assessment tools, frameworks and checklists; Risk and threat assessment & management; Biosafety and security training; Awareness raising; Guidance & best practices. The Toolbox is available at http://ebrf.eu/toolbox.html.

Resources by the Bradford Disarmament Research Centre

Preventing Biological Threats: What You Can Do: A Guide to Biological Security Issues and How to Address Them, edited by Whitby S., Novossiolova T., Walther G. and Dando M. (2015)

The Guide is intended to raise awareness and knowledge of biological security for everyone active in the life sciences, ranging from those engaged in research to those engaged in management and policy-making, both nationally and internationally. The Guide addresses: Threats and Responses; Scientists, Organisations and Biosecurity; Biosecurity and Law Enforcement; States and Biosecurity; and Biosecurity and Active Learning. This publication is available, in English, French and Russian, at https://www.un.org/disarmament/biological-weapons/national-implementation/resource-repository.

Biological Security Education Handbook: The Power of Team-Based Learning, by Tatyana Novossiolova (2016)

This handbook combines teaching material with an active team-based learning approach to empower educators, students and practitioners as they begin to engage with biological security. It aims to supplement the above Guide by providing its users with tips and insights into how to implement its content in different educational settings. This publication is available in Arabic, English, French, Russian and Spanish at https://www.un.org/disarmament/biological-weapons/national-implementation/resource-repository.

Resources by the Federation of American Scientists (FAS)

The Virtual Biosecurity Center (VBC)

The Virtual Biosecurity Center is a "one stop shop" for biosecurity information, education, best practices, and collaboration spearheaded by the FAS. Available at http://www.virtualbiosecuritycenter.org/.

Biosecurity Educational Portal

The FAS maintains a biosecurity education portal featuring relevant educational materials, including case studies. In addition to the case studies in dual use biological research described below, it also features cases studies in agricultural biosecurity, which in its Module 2 examines the safety and security concerns associated with developments in agricultural biotechnology. Available at http://fas.org/programs/bio/educationportal.html.

Case studies in dual use biological research

In order to increase biologists' awareness of biosecurity issues, FAS developed an online tool presenting case studies to help define the issues associated with dual-use research and security in the research lab. The case studies include interviews with researchers whose legitimate scientific work could potentially be used for questionable or harmful endeavours, as well as a historical perspective on their research, bioterrorism, and research regulations; as well as scientific research papers and discussion questions that are meant to raise awareness about the importance of responsible biological research. This tool is available in Chinese, English and French at https://fas.org/biosecurity/education/dualuse/index.html.

Resources by Biosecure

Biosecurity for the Next Generation: Responding to biological risks in the 21st century

In conjunction with Bath University and funded by the UK Foreign and Commonwealth Office, Biosecure developed an open online course on biosecurity for life science students. The course is free to join and can be accessed via the FutureLearn platform at www.futurelearn.com/courses/biosecurity. Spread over six weeks, the course is specifically designed to provide students and young professionals in the biosciences, bioengineering and security sectors with a comprehensive understanding of: the biosecurity challenges inherent in the life sciences; local, national and international responses to these biological risks; the role and contribution of biological scientists and engineers in making sure that science and technology is used safely and securely. All course materials, including videos, quizzes and case studies, are free to download and share, and can be incorporated into university courses as either standard teaching tools or the course can be used as part of a flipped learning approach.

UNODA Meetings Place

The UNODA Meetings Place website contains the official documents of the Review Conferences, the Meetings of States Parties and the Meetings of Experts. Many of these documents address BWC national implementation.

UNODA website

The BWC section of the UNODA website contains information on national implementation and a resource repository, which contains links to resources that may facilitate national implementation of the BWC.

ANNEX 4 – LIST OF RELEVANT ASSISTANCE PROGRAMMES AND INITIATIVES

General

States Parties' assistance activities

The BWC Implementation Support Unit acts as a clearing house for assistance with national implementation.

The ISU administers and maintains a database containing requests for, and offers to, provide assistance, available at https://bwc-articlex.unog.ch. This database is intended to be used by States Parties to match requests with offers for assistance, and then make arrangements for collaboration. The ISU may also, on request, facilitate the exchange of information among States Parties relating to the database and any resulting cooperation and assistance activities. States Parties may use the database to research assistance and cooperation offers and requests made under Article X.

UNODA assistance

UNODA provides practical assistance and capacity-building in the disarmament and non-proliferation area mainly through its three regional centres.

- **The UN Regional Centre for Peace, Disarmament and Development in Latin America and the Caribbean (UNLIREC).** UNLIREC is based in Lima, Peru, and was created to support Latin American and Caribbean States in the implementation of peace and disarmament measures and to promote economic and social development. UNLIREC has in-house disarmament policy, legal and technical experts who are fully bilingual in Spanish and English, who are responsible for conceptualizing and implementing all project activities, including bolstering trade controls over items of proliferation concern.
- **The UN Regional Centre for Peace and Disarmament in Asia and the Pacific (UNRCPD).** UNRCPD is based in Kathmandu, Nepal, and is mandated to provide, on request, substantive support for initiatives and other activities, mutually agreed upon by the Member States of the Asia-Pacific region, for the implementation of measures for peace and disarmament, and to coordinate the implementation of regional activities

in Asia and the Pacific. The Centre focuses its activities in three main areas: providing capacity building and technical assistance, creating and participating in dialogue fora, and engaging in outreach and advocacy on disarmament issues.

- The UN Regional Centre for Peace and Disarmament in Africa (UNREC). UNREC is based in Lome, Togo, and is mandated to provide, upon request, substantive support for initiatives and other efforts of African Member States towards the realization of measures of peace, arms limitation and disarmament in the region. As part of its activities, UNREC provides assistance, at their request, to Member States and regional and subregional intergovernmental and civil society organisations in Africa to foster peace, security, disarmament, non-proliferation and arms control of weapons of mass destruction, including the prevention of the proliferation of weapons of mass destruction to non-State actors.

European Union assistance

European Union Joint Actions / Council Decisions in support of the BWC

Since 2006 the European Union has supported the BWC through six instruments. The current EU Council Decision 2019/97 was adopted in January 2019 in the framework of the EU's Strategy against the Proliferation of Weapons of Mass Destruction. In the framework of the Council Decision, assistance is provided to States interested in joining the BWC as well as to States Parties keen to strengthen the implementation of the BWC at the national level.

In November 2021, the EU adopted Council Decision 2021/2072 in support of building resilience in biosafety and biosecurity through the BWC. This two-year long project will complement Council Decision 2019/97 by placing a particular focus on strengthening biosafety and biosecurity capabilities in Africa, building capacity for BWC National Contact Points, facilitating the review of developments in science & technology of relevance to the convention and broadening support for voluntary transparency exercises.

For more information, please see https://www.un.org/disarmament/biological-weapons/eu-support-to-the-bwc.

EU CBRN Risk Mitigation Centres of Excellence (CoE)

The EU CBRN Risk Mitigation Centres of Excellence (CoE) initiative is the EU's main international cooperation instrument supporting security initiatives and peace-building activities in Partner Countries. The initiative has 61 Partner Countries and eight Regional Secretariats. The aim of the Initiative is to mitigate

risks and strengthen an all-hazards security governance in Partner Countries of the EU following a voluntary and demand-driven approach. Under the responsibility of CBRN National Focal Points and their inter-ministerial CBRN National Teams, EU support is provided to implement a wide range of CBRN Risk Mitigation activities including needs and risk assessments, national and regional action plans, trainings, Train-the-Trainer modules, table-top and real-time (including cross-border) field exercises. For more information, see https://europa.eu/cbrn-risk-mitigation/index_fr.

United States assistance

The United States provides a wide range of assistance to other States Parties to support BWC implementation, including for the development of biorisk assessments, and biosafety and biosecurity self-assessments and implementing measures. At the Meeting of Experts on Strengthening National Implementation, which took place on 3 September 2021, the United States announced the launch of the "U.S. Project to Strengthen BWC National Implementation", see BWC/MSP/2020/MX.3/WP.2. For additional information about specific assistance, contact ISN-BPS-DL@state.gov.

VERTIC NIM Programme

VERTIC's National Implementation Measures (NIM) Programme provides tailored advice to interested States for adherence to and implementation of certain international instruments, including those focusing on the non-proliferation of chemical, biological, nuclear and radiological weapons and the security of related materials. As part of its activities, VERTIC is involved in raising awareness of State's obligations under international instruments through workshops and the dissemination of training and information materials. VERTIC provides tailored advice to States that are ratifying or acceding to amongst others the BWC, also offering advice for developing legislative or UN Security Council resolution 1540 (2004) national action plans. VERTIC further regularly undertakes comprehensive analysis (legislation surveys) of an interested State's existing laws and regulations for implementation of the BWC, and other instruments such as the International Health Regulations (IHR) and UNSCR 1540. The analysis is using templates developed in-house by VERTIC. Moreover, VERTIC provides tailored advice for drafting new legislation during workshops in capitals using legislative drafting tools developed in-house and supplying examples of legislation in force to identify best legislative and regulatory practices. For more information, see https://www.vertic.org/programmes/biological-weapons-and-materials/legislative-assistance-provider/.

Transfer controls

The WCO Strategic Trade Control Enforcement (STCE) Programme

The STCE Programme aims to help WCO Member States meet their obligations under Security Council resolution 1540 (2004), and better secure and facilitate global trade, consistent with the principles of the SAFE Framework of Standards, better protect their ports and territory from exploitation by criminal actors, and heighten the security of their nation and of their trade partners. Under the Programme, WCO Member States may seek technical assistance on STCE. The Programme focuses on six fundamental areas: organisation of STCE Train-the-Trainer workshops for accreditation of experts; delivering STCE trainings based on the WCO Training Curriculum; operation of the STRATComm communication platform on 24/7/365 basis and the further development of the system; organisation of further STCE-related law enforcement operational exercises; enhancement of industry outreach at the global and national level; and development of STCE seizures reporting in the CEN System. For more information, see http://www.wcoomd.org/en/topics/enforcement-and-compliance/activities-and-programmes/security-programme/stce-project.aspx

As a part of the Programme, the WCO published a comprehensive *STCE Implementation Guide* to assist its Members in developing, reviewing, and implementation of their STCE processes and procedures, and to provide a framework for the training curriculum. The *Guide* is available in Arabic, English, French, Russian and Spanish from http://www.wcoomd.org/en/topics/enforcement-and-compliance/instruments-and-tools/guidelines/wco-strategic-trade-control-enforcement-implementation-guide.aspx.

Biosafety and biosecurity, including bioemergency preparedness and response

Biosafety associations

Biosafety associations provide a forum for exchanges and collobration amongst relevant professionals. Amongst them:

- American Biological Safety Association (ABSA) http://www.absa.org/
- Asia-Pacific Biosafety Association (A-PBA) http://www.a-pba.org/
- European Biological Safety Association (EBSA) http://www.ebsaweb.eu/
- International Federation of Biosafety Associations (IFBA) http://www.internationalbiosafety.org

Food and Agriculture Organization (FAO) http://www.fao.org

FAO gives practical help to developing countries through a wide range of technical assistance projects. FAO provides technical assistance directly to its Member countries in areas such as building or strengthening national biosafety systems, including development and implementation of regulations, training of personnel of regulatory bodies in risk analysis of GMOs, communication and public participation in biosafety-related decision making, and upgrading of laboratory capacities. FAO also hosts the Secretariats of a number of intergovernmental bodies and treaties that deal with some biotechnology-related issues, including the International Plant Protection Convention (IPPC).

For more information on FAO activities relating to biotechnology, see http://www.fao.org/biotechnology

For more information on FAO activities on food safety, see http://www.fao.org/food-safety/en/

For more information on FAO activities relating to animal health, see http://www.fao.org/animal-health/en/

Global Environment Facility (GEF) https://www.thegef.org

The Global Environment Facility (GEF) provides funding to build country capacity to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Protocol aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

Information on the Protocol and the decisions and initiatives taken and mechanisms established at the global, regional and national levels to facilitate the strengthening of the capacities of Parties can be found at http://bch.cbd.int/protocol.

Global Health Security Agenda (GHSA) https://ghsagenda.org

The GHSA was launched in February 2014 to advance a world safe and secure from infectious disease threats, and to bring together nations from all over the world to make new, concrete commitments, and to elevate global health security as a national leaders-level priority. Through a partnership of 69 States, international organisations, and non-governmental stakeholders, GHSA seeks to better equip States to prevent, detect and respond to infectious diseases by facilitating collaborative, capacity-building efforts to achieve specific and

measurable targets around biological threats, while accelerating achievement of the core capacities required by the relevant global health security frameworks. One action package (GHSA Action Package Prevent-3) addresses Biosafety and Biosecurity, with the objective for countries to have a whole-of-government national biosafety and biosecurity system in place.

Global Partnership Against the Spread of Weapons and Materials of Mass Destruction https://www.gpwmd.com.

The Global Partnership, which comprises 30 partner countries and the European Union, has established biological security as one of its priority areas. The Global Partnership pursues activities that aim to: secure and account for materials that represent biological proliferation risks; develop and maintain appropriate and effective measures to prevent, prepare for, detect and disrupt the deliberate misuse of biological agents; strengthen national and international capabilities to rapidly identify, confirm/assess and respond to biological attacks; reinforce and strengthen the BWC and other biological disarmament and non-proliferation obligations, principles, practices and instruments; and reduce biological proliferation risks through the advancement and promotion of safe and responsible conduct.

In 2020 the Global Partnership Against Weapons and Materials and Weapons of Mass Destruction launched the Signature Initiative to Mitigate Biological Threats in Africa. In this framework, the BWC Implementation Unit implements a four-year project from 2022 to 2026, that comprehensively supports requests from African countries in their efforts to strengthen the Convention's implementation and promote its universalization. For more information see https://www.un.org/disarmament/global-partnership-support/.

World Health Organization (WHO) https://www.who.int

The WHO supports Member States in their efforts to implement the International Health Regulations (2005) into national legislation and ensures they have the core capacities for surveillance, preparedness and response towards all public health threats.

The WHO also supports a network of National IHR Focal Points, through trainings and capacity building. National IHR Focal Points are national offices or centres (not individual people) that are accessible at all times for IHR-related communications with WHO and relevant sectors within the country.

For more information, see https://www.who.int/activities/supporting-national-implementation-of-international-health-regulations.

World Organization for Animal Health (WOAH) http://www.oie.int

The WOAH has developed the Performance of Veterinary Services (PVS) Pathway, a capacity building platform for the sustainable improvement of national veterinary services. The PVS Pathway empowers national veterinary services by providing them with a comprehensive understanding of their strengths and weaknesses using a globally consistent methodology based on international standards. This enables countries to take ownership and prioritise improvements to their animal health system.

The absence of quality veterinary legislation has been a frequent finding in PVS Pathway Evaluation missions and the Veterinary Legislation Support Programme (VLSP) was developed to provide countries with the opportunity to have their legislation in the veterinary domain systematically reviewed by VLSP experts, identify gaps and weakness in that legislation, to strengthen their capacity in legal drafting and develop new legislation.

More information on the PVS Pathway can be found at https://www.oie.int/solidarity/pvs-pathway/.

More information on the PVS Pathway Veterinary Legislation Support Programme (VLSP) can be found at https://www.woah.org/en/what-we-offer/improving-veterinary-services/pvs-pathway/.

Implementation of Security Council resolution 1540 (2004)

1540 Committee

The 1540 Committee has a match-making role to facilitate assistance by others for implementation of the UN Security Council resolution 1540. The Committee matches assistance requests from States with offers from States or international, regional or subregional organisations in a position to provide assistance. One aspect of the match-making function is to provide information from which assistance projects can be developed and successfully implemented. In addition to its clearinghouse role to facilitate assistance by others, the 1540 Committee provides assistance directly on certain issues such as on the development of National Implementation Action Plans, peer reviews, matrix gap analysis, and reporting.

The 1540 Committee posts on its website a summary of assistance requests (see at https://www.un.org/en/sc/1540/assistance/request-for-assistance/

current-requests-from-member-states.shtml), as well as a list of States and international organisations offering assistance (see at https://www.un.org/en/sc/1540/assistance/offers-of-assistance.shtml).

A database of available 1540 related assistance and support initiatives is also maintained by the Stimson Center at https://1540assistance.stimson.org.

States Parties seeking assistance for the drafting of implementing legislation, regulations and guidelines for the implementation of their obligations under resolution 1540 may submit a request for assistance using the assistance template available on the 1540 Committee website at https://www.un.org/en/sc/1540/assistance/assistance-template.shtml.

For more information on the assistance provided for the implementation of resolution 1540, see at https://www.un.org/en/sc/1540/assistance/general-information.shtml.

ANNEX 5 – REFERENCES

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