Regulatory Guidelines for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540

TABLE OF CONTENTS

INTRODUCTION

VERTIC has developed these *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 1972 Biological and Toxin Weapons Convention (BWC), as well as the biological weapons-related provisions of UN Security Council Resolution 1540. These *Guidelines* are not a set of model regulations, but rather suggestions, tips and links to examples of best practices, which States are free to review and utilize, taking into account their own legal framework and traditions, level of biotechnological development and other national circumstances. Regulations take time and care to develop and users of these *Guidelines* may wish to prioritise certain regulations over others starting with, for example, establishing a Responsible Authority.

For simplicity and consistency, the structure of these *Guidelines* follows Parts C and D of VERTIC's *Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540* (hereinafter *Sample Act*)(available at www.vertic.org). For most States, Parts A and B of the *Sample Act* will not require any supplemental regulations or administrative measures. Part E enables a State to promulgate any additional regulations that are not immediately identified under the *Sample Act*.

Part I of these *Guidelines* focuses on biosecurity (corresponding to Part C of VERTIC's *Sample Act*). The *Guidelines* provide guidance on the establishment of control lists for biological agents, toxins, and dual-use equipment and technology, including intangible technology. They also include guidance on the establishment of a licensing system for controlled agents and toxins, measures to monitor their internal and international transfers, measures to secure their transportation, and other laboratory biosafety/biosecurity measures.

Part II of these *Guidelines* focuses on enforcement (corresponding to Part D of VERTIC's *Sample Act*). The *Guidelines* include guidance on establishing a Responsible Authority for the BWC and 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 (e.g., Biological Emergency Response and Investigation Support System (BERISS)). They also provide guidance on record-keeping and reporting, national inspections, and investigations.

These *Guidelines* are not static, and VERTIC will continue to develop and revise them as necessary.

VERTIC is in a position to assist with the development of laws and regulations for national implementation of the BWC, if requested. This service is free of charge.

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VERTIC is an independent, non-profit making, non-governmental organization located in London, United Kingdom. VERTIC promotes effective and efficient verification as a mean of ensuring confidence in the implementation of international agreements.

VERTIC's National Implementation Measures (NIM) Programme was developed to assist States in understanding what measures are required at the national level to comply with obligations in a wide range of nuclear, chemical and biological weapons treaties and UN Security Council resolutions and how to implement them.

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PART I **BIOSECURITY**

States Parties are entitled under the BWC to conduct peaceful activities involving biological agents and toxins on their territories. Every day, researchers and technicians carry out research and development, vaccine production and diagnostic activities, in ways that are essential for promoting human, animal and plant health. In some cases, however, these activities may pose a risk to public, animal and plant health, the environment and security if they involve particularly lethal agents and toxins that are not effectively and consistently regulated. Biosecurity measures such as the ones discussed below, in Guidelines 1 to 6, will help ensure that accidental or intentional releases of such agents or toxins are prevented, and that the life scientists working with them will do so in a safe and secure manner and environment. The adoption of biosecurity measures by regulation ensures that governments will have the flexibility to modify them as new needs and risks arise or change.

1. Controlled agents and toxins

A robust biosecurity framework should start with a list of controlled agents and toxins (*Sample Act*, Section 9), which may only be used by licensed entities and individuals for prophylactic, protective or other peaceful purposes. This list should also serve as the basis for controlling internal and international transfers as discussed in Guideline 4 below.

There are two approaches to the adoption of a control list. The first consists of a State establishing and maintaining its own tailored list of biological agents and toxins, particularly those that pose a significant threat to the country's public health and safety and national security. In preparing this list, a regulator could consider:

- the effect of exposure on human, animal, or plant health, or on animal or plant products;
- the degree of contagiousness and method of transmission;
- the availability and effectiveness of pharmocotherapies and immunisations; and
- any other criteria that the regulator may deem appropriate.

The second approach is based on risk groups. The World Health Organization (WHO) has classified these groups in its *Biosafety Laboratory Manual*, Third Edition, 2004 (see Box 5 below), as follows:

- 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.

Normally, a State would consider including biological agents falling under Risk Groups 3 and 4 in their controlled agents and toxins list.

The benefit of the options discussed above is that any list arising from them would reflect the public, animal and plant health, environmental, and security concerns of the individual State, which may differ to various degrees from the risks posed in other States. At the same time, however, many States have neither the resources nor the capacity to develop these lists without external inputs. There are, nevertheless, good examples of lists of controlled agents and toxins, which are included in Box 1 below.

Box 1: Examples of lists of controlled agents and toxins

- Australia Group Lists:
  http://www.australiagroup.net/en/controllists.html
- European Union 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
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R0428:20120615:EN:PDF
- United Kingdom Anti-Terrorism, Crime and Security Act 2001, Part 7 (Security of Pathogens and Toxins):
  http://www.legislation.gov.uk/ukpga/2001/24/contents
  Schedule 5:
  http://www.legislation.gov.uk/ukpga/2001/24/schedule/5
- United Kingdom Health and Safety Executive Approved List of Biological Agents:
  http://www.hse.gov.uk/press/2004/e04078.htm
- United States Department of Health and Human Services (HHS) and Department of Agriculture (USDA) list of selected agents and toxins:
  http://www.selectagents.gov/index.html

2. Controlled equipment and technology

States should also consider adopting and maintaining a list of biological equipment and technology, including intangible technology, which would be subject to international transfers control (internal control of these dual-use items is an onerous administrative burden and is therefore not recommended). This list would be known as the controlled equipment and technology list (*Sample Act*, Section 10). There are already publicly available lists that are widely used, which can make this process easier; examples are in Box 2 below.

Box 2: Examples of lists of controlled equipment and technology

- Australia Group Lists:
  http://www.australiagroup.net/en/controllists.html
- European Union 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
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R0428:20120615:EN:PDF

3. Licensing for activities involving controlled agents and toxins

Licensing regulations (*Sample Act*, Section 11) will help ensure that activities involving especially dangerous biological agents and toxins are monitored and controlled by government, without unduly burdening the peaceful work of life scientists, researchers and technicians. Licensing enables a

government to have a database of who is holding or working with which controlled agents or toxins, and for what purpose. These regulations will require any legal or governmental entity or individual engaged in the development, acquisition, manufacture, possession, transfer, storage, or use of controlled agents or toxins to obtain a license from the relevant government authority. This may be, in some States, the Responsible Authority responsible for implementation of the BWC (see Guideline 7 below).

Licensing should also be considered for any work involving genetic modification of microorganisms[1].

States should include in their regulations the following elements:

- The name and full contact details of the governmental authority responsible for granting, denying, suspending or revoking licenses;
- The form of the license:
    - Licensee's name and full contact details (this will be an entity and/or individual(s));
    - Entity ownership information, including any changes in ownership;
    - Name and full contact details of any facility or facilities under the licensed entity's control where activities involving controlled agents or toxins take place;
    - Which controlled agents or toxins are being used by the licensee(s);
    - A description of the licensee's activities involving controlled agents or toxins;
    - The name of the Compliance Officer(s) in the licensed entity's facility or facilities who will be responsible for liaison between the entity and the facilities; the full contact details for the Compliance Officer(s); the responsibilities of the Compliance Officer(s);
- Conditions under which licenses will be granted, for example:
    - the licensee must demonstrate that they meet certain laboratory biosafety and biosecurity conditions (discussed in Guideline 6 below);
    - licensed individuals must be qualified to work with the controlled agents and toxins listed in the license;
    - the licensed entity must undertake personnel background checks of their licensed individuals (e.g., criminal, financial, previous employers, educational institutions);
- Conditions under which a license may be denied, suspended or revoked (violations of any applicable legislation or regulations, violation of the terms of a license, etc.);
- Individuals who are, by law, prohibited from receiving a license (e.g., convicted felons, individuals with drug or alcohol addictions, known terrorists, etc.);
- A database of licensees where the data in the form of the license (discussed above) is entered and maintained in a searchable and secure manner; the regulations should designate the governmental authority responsible for maintaining and updating the database (for most States this would be the same authority that is responsible for issuing licenses);
- Procedures for reporting theft, loss or release (whether intentional or accidental) to the governmental authority responsible for licensing including:
    - a form for reporting the theft, loss or release and procedures for including this in the licensing authority's database (described above) including:
        - the date and time when the theft, loss or release was first discovered;

[1] See, for example, the United Kingdom's Genetically Modified Organisms (Contained Use) Regulations 2000, and amendments (available at http://www.legislation.gov.uk/uksi/2000/2831/contents/made).

        - the name of the individual(s) who discovered the irregularity, including contact details, functions and responsibilities;
        - the name of the controlled agent or toxin in question as well as a description of any activities involving the agent(s) or toxin(s);
        - steps being taken to recover the material;

    - a time limit for reporting the theft, loss or release and clear instructions on where the form is to be sent and to whom (with full contact details);
    - a requirement that the licensee and Compliance Officer also inform local law enforcement authorities or the licensing authority who in turn would contact and liaise with law enforcement authorities;
    - in the event of a release, the additional requirement that public, animal or plant health officials, as well as the appropriate law enforcement authorities, are contacted immediately to facilitate outbreak containment (see Box 8 below).

4. Monitoring internal and international transfers of controlled agents and toxins and controlled equipment and technology

States should monitor internal and international transfers of controlled agents and toxins, as well as international transfers of controlled equipment and technology, included in any control lists (see Guidelines 1 and 2 above; *Sample Act*, Sections 12 and 13). This monitoring is normally accomplished through a system of transfers permits and a registry. For some States, this function would fall within the responsibility of an existing export-import control authority or could be assigned to the Responsible Authority for implementation of the BWC, discussed in Guideline 7 below.

States should clarify by regulation:

- the governmental authority responsible for granting, denying, suspending or revoking internal and international transfers permits, and its full contact details;
- the establishment of a secure and searchable registry of all internal and international transfers, which would contain the data contained in any forms submitted to the governmental authority for a transfers permit (see below), and the authority responsible for maintaining and updating the registry (for most States this would be the same authority that issues the transfers permits).

In addition to these, States may need more detailed regulations unique to internal and international transfers.

For internal transfers, States should include in their regulations:

- the form for a transfer with the following information:

    - names and full contact details of the transferring parties (senders/recipients), including details for the transferring entities, facilities and individuals, as well as a statement requiring copies of their licenses to engage in activities involving controlled agents and toxins to be attached (see Guideline 3 above);
    - the type and quantity of controlled agents or toxins to be transferred internally and a statement explaining why the internal transfer is taking place;
    - a description of any risks associated with the internal transfer, and steps taken to mitigate these risks;
    - details on the domestic carrier to be used, including their full contact details (so that the transfers authority can confirm that the carrier is approved (see Guideline 5 below);

- conditions under which internal transfers permits will be granted, for example:

    - the transferor must demonstrate that they will meet national packaging, labelling and shipping standards for controlled agents and toxins (see Guideline 5 below);
    - the recipient must be licensed or authorized under the regulations to handle controlled agents and toxins;

- conditions under which a permit may be denied, suspended or revoked (violations of any applicable legislation or regulations, violation of the terms of a license or permit, not being in possession of a valid license to engage in activities involving controlled agents and toxins, etc.);
- individuals who are, by law, prohibited from receiving a permit (e.g., convicted felons, individuals with drug or alcohol addictions, known terrorists, etc.);
- procedures for reporting theft, diversion, loss or release (whether intentional or accidental) to the governmental authority responsible for issuing permits including:

    - a form for reporting the theft, diversion, loss or release and procedures for including this in the transfers authority's registry (described above) with:

        - the date and time when the theft, diversion, loss or release was first discovered;
        - the name of the individual(s) who discovered the irregularity, including contact details, functions and responsibilities;
        - the names and full contact details for the sending and receiving parties, as well as for the domestic carrier;
        - the name(s) of the controlled agent(s) or toxin(s) in question;
        - steps being taken to recover the material;

    - a time limit for reporting the theft, diversion, loss or release and clear instructions on where the form is to be sent and to whom (with full contact details);
    - a requirement that the permit holder also inform local law enforcement authorities or the internal transfers authority who in turn would contact and liaise with law enforcement authorities;
    - in the event of a release, the additional requirement that public, animal or plant health officials, as well as the appropriate law enforcement authorities, are contacted immediately to facilitate outbreak containment (see Box 8 below).

For international transfers of controlled agents and toxins or controlled equipment and technology, a State should clarify by regulation:

- the types of transfers permits to be made available, such as ones for:

    - Import[2]
    - Export[3]
    - Re-export[4]
    - Transhipment[5]

[2] To bring into the physical jurisdiction or customs boundary of a State items coming from a foreign State.
[3] The actual shipment or transmission of items out of the physical jurisdiction or customs boundary of a State.
[4] Actual shipment or transmission of items from one foreign State to another where the items in question had themselves been imported and where those items were originally subject to export control laws or regulations of another State.

- Transit[6]

- the forms for the transfers permits (based on the type of transfer above) with the following information:

    - names and full contact details of the sending and receiving parties, at all steps of the transfer, including all details for the domestic entity, facility and individual, as well as a statement requiring copies of their licenses to engage in activities involving controlled agents and toxins (see Guideline 3 above);
    - the types and quantities of controlled agent(s) or toxin(s) or controlled equipment and technology to be transferred internationally as well as a statement explaining why the transfer is taking place;
    - details on any carriers to be used at all steps of the transfer as well as their full contact details (so that the governmental authority can confirm that the carriers are approved (see Guideline 5 below);

- any transfers restrictions, for example, prohibitions on any transfers to or from certain countries;
- conditions under which international transfers permits will be granted, for example, the transferor must demonstrate that the transfer will meet national and international packaging, labelling and shipping standards for controlled agents and toxins (see Guideline 5 below);
- conditions under which a permit may be denied, suspended or revoked (violations of any applicable legislation or regulations, violation of the terms of a license or permit, not being in possession of a valid license to engage in activities involving controlled agents and toxins, etc.);
- individuals who are, by law, prohibited from receiving a permit (e.g., convicted felons, individuals with drug or alcohol addictions, known terrorists, etc.);
- procedures for reporting theft, diversion, loss or release (whether intentional or accidental) to the governmental authority responsible for issuing permits including:

    - a form for reporting the theft, diversion, loss or release and procedures for including this in the transfers authority's registry (described above) with:

        - the date and time when the theft, diversion, loss or release was first discovered;
        - the name of the individual(s) who discovered the irregularity, including contact details, functions and responsibilities;
        - the names and full contact details for the sending and receiving parties, as well as for the domestic and international carriers;
        - the name(s) of the controlled agent(s) or toxin(s) or controlled equipment or technology in question;

    - a time limit for reporting the theft, diversion, loss or release and clear instructions on where the form is to be sent and to whom (with full contact details);
    - a requirement that the permit holder also inform local law enforcement authorities or the international transfers authority who in turn should contact and liaise with national law enforcement authorities as well as the authorities of the State to or from which the controlled agent or toxin, or controlled equipment or technology, was being transferred;

[5] After goods have been unloaded or in any way removed from the means of transportation by which they came into a State, their loading, placing on board or within or upon the same or any other means of transportation with a view to being carried outside the boundaries of that State.
[6] The carriage of goods across the territory and out of a State using the same means of transportation by which they entered that State and without their unloading.

- in the event of a release, the additional requirement that public, animal or plant health officials, as well as the appropriate law enforcement authorities, are contacted immediately to facilitate outbreak containment (see Box 8 below);

- a requirement that controlled agents or toxins or controlled equipment or technology may only be transferred to individuals, entities or facilities in States with equally robust legislation and regulations governing these sensitive materials;
- a requirement for an end-user certificate (prepared by the recipient party), to be included with the appropriate transfer form (discussed above), containing:

    - a statement that the controlled agent or toxin or controlled equipment or technology will only be used for lawful purposes;
    - a statement that the controlled agent or toxin or controlled equipment or technology will not be retransferred;
    - the type and quantity of controlled agent or toxin, or a description of the controlled equipment or technology, to be transferred;
    - the end-use of the controlled agent or toxin or controlled equipment or technology to be transferred; and
    - the name(s) and location(s) of the end-user(s) and any intermediaries;

- a description of risk (risk assessment) by the party requesting a permit with an evaluation of the safety and security of the transfer, to be included with the appropriate transfer form (discussed above).

The EU example of export control regulations, as well as related forms, are noted in Box 3 below.

Box 3: Examples of regulations and forms for sensitive goods export permits

- European Union 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 (*see especially the annexes*):
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R0428:20120615:EN:PDF

5. Secure transport of controlled agents and toxins

Safe and secure transport of controlled agents and toxins (*Sample Act*, Section 14) is essential to avoid the risk of biological weapons proliferation, as well as accidental releases of infectious substances. A State's regulations, issued further to any legislation adopted to implement the BWC, should ensure that licensed entities and individuals, as a condition to receiving a transfers permit (discussed above in Guideline 4), undertake packaging, labelling and shipping of controlled agents and toxins in compliance with national and international safety and security standards.

A State may wish to designate by regulation its Ministry of Transport (or equivalent) as the authority responsible for certifying carriers.[7] A State may also wish to specify in its regulations that only certified carriers are approved to transport controlled agents and toxins, and that they must be in possession of an official duplicate copy of a transfer permit for a particular shipment.

[7] A State may also wish to include a representative of the Ministry of Transport in the Responsible Authority (see Guideline 7).

A State may also wish to clarify by regulation that the Ministry of Transport will establish the conditions under which carriers must transport controlled agents and toxins, including, for example, the technical specifications for transport vehicles and markings; safety and security measures at the transfer depots; the licensing, training and vetting of personnel; and shipment tracking (through electronic tagging, bar coding, signature and identification of recipient, etc.).

Examples of transport guidelines for infectious substances are already available to States for preparing national regulations governing the safe and secure transport of controlled agents and toxins (Box 4).

Box 4: Guidelines for secure transportation of controlled agents and toxins

- The International Air Transport Association's (IATA) *Guidance Document for Infectious Substances*, *DG Regulation on the Classification of Infectious Substances* and *Packing Instruction 650 (Toxic and Infectious Substances)*: http://www.iata.org/whatwedo/cargo/dgr/Pages/infectious_substances.aspx

- The World Health Organization's (WHO) *Guidance on regulations for the Transport of Infectious Substances,* 2008: http://www.who.int/ihr/biosafety/publications_WHO_HSE_EPR_2008_10/en/index.html

6. Laboratory biosafety and biosecurity

As a condition to receiving a license to engage in activities involving controlled agents and toxins (Guideline 3), a State should require entities, facilities and individuals to demonstrate to the licensing authority that they comply with applicable national and international biosafety[8] and biosecurity[9] standards for laboratories.

WHO has published a comprehensive resource, the *Biosafety Laboratory Manual* (see Box 5 below), which makes drafting laboratory biosafety regulations much clearer for States. Part I of this manual, in particular, goes into great detail on biosafety guidelines, which relate to the four risk groups discussed in Guideline 1. WHO has also identified the corresponding laboratory type, laboratory practices and safety equipment for each biosafety level. A table with this information can be found on page 1 of the *Biosafety Laboratory Manual*.

The licensing authority responsible for monitoring activities involving controlled agents and toxins should require entities, facilities and individuals to demonstrate that they are complying, where appropriate, with biosafety measures for activities at Biosafety Level 3 (BSL 3 – containment laboratory) or Biosafety Level 4 (BSL 4 – maximum containment laboratory). In practice, this would mean that BSL 1 to 3 measures must apply to a containment laboratory and BSL 1 to 4 measures to a maximum containment laboratory.

[8] *Laboratory biosafety* is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. (*Biosafety Laboratory Manual*, Third Edition, WHO, 2004).

[9] *Laboratory biosecurity* refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins. (*Biosafety Laboratory Manual*, Third Edition, WHO, 2004).

Box 5: Laboratory biosafety measures

- *Biosafety Laboratory Manual*, Third Edition, WHO, 2004. This manual is available in several languages at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5th Edition, Centers for Disease Control and Prevention, 2007: http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

WHO has published another excellent resource, the *Biorisk Management - Laboratory Biosecurity Guidance* (see Box 6 below), which makes drafting laboratory biosecurity regulations clearer for States. The *Guidance* applies to human, veterinary and agricultural laboratories. Parts 4 (biorisk management), 5 (countering biorisks) and 6 (laboratory biosecurity programme) are particularly relevant to States engaged in preparing laboratory biosecurity regulations. Other useful resources are listed in Box 6.

Box 6: Laboratory biosecurity measures and biorisk management

- *Biorisk Management - Laboratory Biosecurity Guidance*, WHO, September 2006: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/
- *OECD Best Practice Guidelines on Security for Biological Resource Centres (BRCS)*, OECD, 2007: http://www.oecd.org/dataoecd/6/27/38778261.pdf
- *Handbook of Applied Biosecurity for Life Science Laboratories*, SIPRI, 2009: http://books.sipri.org/product_info?c_product_id=382#
- *Laboratory Biorisk Management Standard, European Committee for Standardization (CEN)*, February 2008: ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf
- Laboratory Biosecurity Training, Centers for Disease Control and Prevention (online course): http://www.cdc.gov/od/ohs/biosecurity_training/page2790.html

PART II ENFORCEMENT

States will require a robust set of measures to ensure that the biosecurity regulations discussed in Part I above are effectively implemented and enforced. The guidelines below follow the structure of Part D of VERTIC's *Sample Act*, and provide States with further guidance on the establishment or designation of governmental bodies responsible for implementation of the BWC and biological incident response, as well as measures for monitoring compliance through record-keeping and reporting, inspections and investigations.

7. Responsible Authority

The Sixth Review Conference of the States Parties to the BWC encouraged its members to designate a national focal point for co-ordinating national implementation of the Convention, and for communicating with other States Parties and relevant international organizations.[10] A similar arrangement is called for in the Chemical Weapons Convention (CWC), in Article VII, paragraph 4 (see Box 7).[11] In VERTIC's *Sample Act*, the establishment or designation of a Responsible (or National) Authority for the BWC is provided for in Section 15.

As a first step, a State should assess the scope of its national implementation requirements; it will then be in a better position to decide whether to designate an existing entity as the Responsible Authority for the BWC, or to create a new agency. A State could choose to adopt a centralized structure, within which one entity assumes all the responsibilities and functions related to implementation of the BWC, such as a government ministry or department. Alternatively, a State may choose to adopt a decentralized structure, whereby the Responsible Authority co-ordinates the implementation activities of all relevant governmental bodies and has overall responsibility for international co-operation with regard to the BWC. Governmental bodies that may already have responsibility for issues falling under the Convention might include: a national health authority responsible for licensing laboratories; a trade ministry that authorizes imports and exports of dual-use items; and a foreign ministry that may already be liaising with the BWC Implementation Support Unit or be involved in Geneva-based BWC meetings and conferences.

Some States have taken a different approach and combined their Biological and Chemical Weapons Conventions focal points into one governmental entity as a matter of efficiency and effectiveness, and have added responsibilities under the BWC to those of their existing CWC National Authority.

Each State is free to determine its Responsible Authority's functions and responsibilities, which are normally governed by law and regulation. Some functions and responsibilities, nevertheless, are particularly important.

At the international level, the Responsible Authority should:

- act as a national point of contact for the BWC Implementation Support Unit, and inform the Unit of its name and full contact details[12];

[10] *Final Document of the Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, 8 December 2006, BWC/CONF.VI/6.
[11] As at 20 January 2011, 182 out of 188 States Party to the Chemical Weapons Convention have designated or established their National Authority.
[12] BWC Implementation Support Unit (United Nations Office for Disarmament Affairs, Geneva Branch): http://www.unog.ch/80256EE600585943/(httpPages)/16C37624830EDAE5C12572BC0044DFC1?OpenDocument.

- provide data and information relevant to the fulfilment of its international obligations to other States Parties and international organizations; this includes gathering any necessary information to prepare Confidence-Building Measure (CBM) returns for submission to the BWC Implementation Support Unit (see Guideline 9);
- share experiences and extend assistance to other States pertaining to implementation of the BWC;
- participate in BWC meetings such as Review Conferences and any other intersessional meetings.

At the national level, the Responsible Authority should:

- develop and promulgate lists of controlled agents and toxins and controlled equipment and technology (see Guidelines 1 and 2);
- process licenses for activities involving controlled agents and toxins (see Guideline 3);
- issue and monitor compliance with permits for internal and international transfers of controlled agents and toxins and controlled equipment and technology (see Guideline 4);
- create and maintain (or coordinate with if appropriate) a national system to respond to biological incidents (see Guideline 8);
- establish a national system to monitor and verify activities in authorized facilities (see Guidelines 9 and 10);
- propose and support the adoption of legislative and other administrative or regulatory measures to implement the BWC;
- supervise and monitor the enforcement of legislation and regulations;
- advise the prime minister or head of government on any BWC-related issues;
- report annually to the parliament or national assembly on its activities;
- coordinate and assist with any of the tasks above attributed to any other government bodies; and
- conduct or facilitate awareness-raising, education, outreach and training vis-à-vis the BWC, biosafety and biosecurity, national implementing legislation and other measures, and codes of conduct for scientists, with the academic and industry communities.

Certain government departments, ministries or agencies may have specific functions and expertise that are highly relevant to implementation of the BWC, and they could be tasked to co-operate with the Responsible Authority. This can be accomplished by assigning a representative to the Responsible Authority and by holding regular consultations and meetings. Accordingly, a State may require, by regulation, that representatives of the following ministries or agencies participate in the activities of the Responsible Authority[13]:

- Office of the Prime Minister or Head of Government;
- Office of the Attorney-General (or equivalent);
- Ministries of Agriculture, Defence, Environment, Foreign Affairs, Health, Industry, Interior, Justice and Transport;
- national border control authorities (customs, ports);
- national academy of science;
- national forensic science laboratory;
- national chamber of commerce; and
- national biotechnology industry association(s) or other professional scientific bodies.

Finally, the regulations for the establishment or designation of a Responsible Authority should prescribe:

[13] This list is only illustrative and should be tailored according to the country's constitutional and statutory regimes, circumstances, needs, etc.

- the conduct of meetings of the Responsible Authority;
- the Responsible Authority's budget; and
- the composition, administrative functions and organization of the Responsible Authority's secretariat.

The *Model Decree on the Establishment of a National Authority for Implementing the CWC* prepared by the Organisation for the Prohibition of Chemical Weapons (OPCW) may be particularly useful to States engaged in drafting their regulations for a Responsible Authority for the BWC. VERTIC has also prepared a Fact Sheet on the topic (Box 7).

Box 7: Establishing a Responsible Authority

- *Model Decree on the Establishment of a National Authority for Implementing the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction*: http://www.opcw.org/our-work/national-implementation/implementing-legislation/models-checklists-questionnaires/
- VERTIC Fact Sheet 10—*National Authority for the Biological Weapons Convention*: http://www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/fact-sheets.php

8. Biological Emergency Response and Investigation Support System (BERISS)

In addition to a Responsible Authority, States should consider establishing 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. For the purposes of the *Sample Act* and these guidelines, VERTIC has named this mechanism the Biological Emergency Response and Investigation Support System (BERISS). The BERISS concept arose out of the recognition that few States explicitly require co-ordination and co-operation among their law enforcement, intelligence, and public health and agriculture communities in the event of disease outbreaks.

States that choose to have the BERISS mechanism, provided for in Section 16 of VERTIC's *Sample Act*, would normally require a new government entity to carry out the following responsibilities:

- Manage, co-ordinate and guide the national and local response to incidents associated with biological agents and toxins in co-ordination with the Responsible Authority;
- establish public health and agricultural surveillance and reporting systems with respect to activities involving controlled agents and toxins, in co-ordination with other governmental agencies;
- ensure the effectiveness of a public emergency announcement system;
- ensure the effective training and equipping of law enforcement officers, emergency/first responders and hospitals in responding to incidents involving biological agents and toxins;
- create threat-based medical and public health detection strategies to detect and determine outbreaks associated with biological agents and toxins;
- receive and review classified biological threat intelligence;
- receive and review public health information;
- collect, maintain, and present evidence needed for review of forensic epidemiological investigations and for prosecutions;
- transmit data and information regarding biological emergencies and incidents to the Responsible Authority;

- liaise and co-operate with the World Health Organisation through the National Focal Point for the 2005 International Health Regulations;
- undertake other activities regarding preparation for and response to emergencies involving biological agents and toxins, including co-operation with law enforcement officers;
- liaise with relevant international organisations that can provide advice and assistance; and
- maintain contacts with other State Parties developing their own systems in order to make use of best practice and experience.

Some of these functions may already be adequately covered by existing laws and regulations for law enforcement; human, plant, and animal health and quarantine; disease surveillance; disaster response; intelligence collection and surveillance; information sharing and data protection; security clearances and state secrets; and criminal procedure, including evidence collection and chain of custody. Accordingly, the regulations establishing BERISS and its responsibilities could make reference to these existing measures. However, additional regulations may be necessary to enable BERISS to prepare standard operating procedures and enter into co-operation and co-ordination agreements with intelligence officials, national and local law enforcement and health authorities, as well as with the Responsible Authority.

Regulations may be necessary to require that the following experts participate in the activities of BERISS:

- a representative from the Responsible Authority to act as a liaison with BERISS;
- representatives from the Ministry of Health (and perhaps the Food and Drug Safety Agency), and the Ministries of Agriculture and Environment;
- an emergency medicine practitioner;
- a law enforcement officer, preferably trained to respond to biological emergencies;
- representatives from the national border control authorities (customs and ports);
- an epidemiologist;
- a veterinary scientist;
- a phytosanitary expert;
- specialists in bacterial, toxicological, viral, rickettsial, fungal and prion diseases;
- a media relations specialist; and
- the National Focal Point for the WHO International Health Regulations.

Finally, regulations may be necessary to govern:

- the conduct of BERISS meetings;
- BERISS' budget; and
- the composition, administrative functions and organization of BERISS' secretariat.[14]

In order for BERISS to be effective, its staff will need to be trained in order to carry out their responsibilities in the event of a disease outbreak. Interpol's Bioterrorism Prevention Resource Centre (Box 8) is an excellent resource with links to sites about prevention and response and co-operation among public health and law enforcement authorities.

[14] See Guideline 7.

Box 8: BERISS – training and co-operation

- Interpol's Bioterrorism Prevention Resource Centre (which includes links to materials on, *inter alia*, detection devices, governmental agencies, biocontainment laboratories, decontamination, agents – treatment and surveillance, personal protective equipment): http://www.interpol.int/Crime-areas/Terrorism/CBRNE-programme/Bioterrorism
- Interpol's Bioterrorism Prevention Programme (and *Bioterrorism Incident Pre-Planning & Response Guide*): http://www.interpol.int/Crime-areas/Terrorism/CBRNE-programme/Bioterrorism
- *Biorisk Management - Laboratory Biosecurity Guidance*, WHO, September 2006: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/ (especially Sections 6.2 and 6.3)
- 2005 International Health Regulations (http://www.who.int/ihr/en/)

9. Record-keeping and reporting

A State should require, by law and regulation, that all licensed entities, facilities and individuals maintain records related to any of their activities involving controlled agents and toxins (*Sample Act*, Section 17). Licensees should be able to account for, at any time, any controlled agents or toxins in their possession, from the point when the controlled agent or toxin enters their facility to the point where it is destroyed or transferred elsewhere. This paperwork, whether in hard copy or electronic, should be maintained and archived in such a way that it is readily accessible in the event of an inspection (see Guideline 10) or request for information by the Responsible Authority, and so that the licensee can effectively prepare periodic reports to the Responsible Authority. The regulations should specify for how long these records must be kept. The manuals listed in Box 9 contain clear guidance on the documentation that should be prepared and maintained by licensees to account for any controlled agents or toxins in their possession.

Box 9: Records and archives

- *Biorisk Management - Laboratory Biosecurity Guidance*, WHO, September 2006: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/ (especially Section 5.1)
- *OECD Best Practice Guidelines on Security for Biological Resource Centres (BRCS)*, OECD, 2007: http://www.oecd.org/dataoecd/6/27/38778261.pdf (especially Section 6.6)
- *Handbook of Applied Biosecurity for Life Science Laboratories*, SIPRI, 2009: http://books.sipri.org/product_info?c_product_id=382# (especially Sections 2.3.2 and 2.3.2.1)

States should also regulate record-keeping by carriers that are approved to ship, domestically or internationally, controlled agents and toxins (see Guideline 5). The regulations should require carriers to keep all copies of:

- duplicates of licensee permits for internal and international transfers of controlled agents and toxins or controlled equipment and technology;
- all documents related to the shipping of controlled agents and toxins or controlled equipment and technology (e.g., manifests, bills of lading, etc.);
- carrier certification documents from the Ministry of Transport or government agency responsible for this activity;
- irregularity reports (theft, diversion, loss, release).

The regulations should specify for how long these records must be kept.

States should promulgate regulations authorizing the Responsible Authority to request information from any licensee, apart from their periodic reporting, and specify:

- the official in the Responsible Authority authorized to send such a notice and their full contact details;
- a statement in the notice clarifying why it is being sent;
- the timeframe for the licensee to relay the requested information to the Responsible Authority;
- the contact details for the official to whom the information is to be sent; and
- the information that must be provided to the Responsible Authority along with the format for providing it.

States should promulgate regulations requiring licensees to report periodically to the Responsible Authority and specify:

- how frequently such reports must be prepared and submitted to the Responsible Authority;
- the information that must be contained in them and the format in which the reports must be submitted; and
- the full contact details of the officer responsible for receiving the reports.

Regulations should authorize the Responsible Authority to process reports from licensees, while requiring any data, for release outside the Responsible Authority, to be compiled in the aggregate to protect sensitive business information or research data. The Responsible Authority could be authorized to prepare annual reports to Parliament on implementation of national legislation and regulations to implement the BWC.

Finally, the Responsible Authority should be authorized to prepare and submit national submissions to international bodies, including the BWC Implementation Support Unit. Accurate record-keeping will facilitate the preparation and submission of seven politically-binding Confidence-Building Measures declarations (CBMs) to the Unit including:

- CBM A: Part 1: Exchange of data on research centres and laboratories / Part 2: Exchange of information on national biological defence research and development programmes;
- CBM B: Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins;
- CBM C: Encouragement of publication of results and promotion of use of knowledge;
- CBM D: Active promotion of contacts;
- CBM E: Declaration of legislation, regulations and other measures;
- CBM F: Declaration of past activities in offensive and/or defensive biological research and development programmes;
- CBM G: Declaration of vaccine production facilities.[15]

These submissions are due before 15 April each year.

[15] Additional information on CBMs and downloadable forms are available at: http://www.unog.ch/80256EE600585943/(httpPages)/CEC2E2D361ADFEE7C12572BC0032F058?OpenDocument.

10. Inspections

A State may wish to consider extending the compliance mechanism of record-keeping and reporting for national facilities handling controlled agents and toxins, discussed in Guideline 9, to include inspections (*Sample Act*, Sections 18 and 19).

A State may choose to designate the Responsible Authority as the agency in charge of national inspections, and give it the authority to organize an inspection team. If there are very few facilities handling controlled agents or toxins in its territory, a State may require the Responsible Authority to rely on existing inspectors in the fields of occupational health and safety; food and drug quality; agriculture; hospital, clinic and laboratory certification; or the like to carry out these responsibilities. The Responsible Authority would have to confirm, however, that these inspectors are qualified to operate in containment and maximum containment environments, else facilitate the appropriate training for the small number of inspectors that would be required.

If a State decides to have a domestic inspections capacity, it will need to clarify in the regulations:

- that inspectors are tasked to monitor compliance with licenses and permits issued under national law and regulations, and with the conditions of such licenses and permits; and
- that inspectors must have reasonable access to any facilities where controlled agents or toxins are handled, including all transfer points and carrier depots.

A State should promulgate regulations to confirm that an inspector may:

- search any premises;
- request a warrant to search facilities when access is denied (the regulations may specify warrant procedures unique to these inspections or make reference to existing entry warrant procedures for other types of inspections);
- operate any photographic or video-recording equipment anywhere in or around the premises provided safety regulations in force at the premises permit doing so;
- require the attendance of and question any person whom the inspector considers will be able to assist in the inspection;
- inspect or examine, take samples of, detain or remove any substance or item considered relevant by the inspector (the regulations may specify the procedures for sampling, including chain of custody and sample security);
- require any person to produce for inspection, or to copy, any document that the inspector believes contains any relevant information (licensees should be required to maintain accurate records for this purpose, and the ones below, as discussed under Guideline 9);
- 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;
- use or cause to be used any computer or data processing system to examine any data contained in or available to the computer or system;
- reproduce or cause to be reproduced any record from the data, in the form of a printout or other intelligible output such as electronic copies, and remove the printout or other output for examination or copying;
- have operated any equipment, including electronic equipment located at the premises;
- be accompanied by an expert, as appropriate, chosen by the inspector and authorized by the Responsible Authority; and
- require that any person in control of the premises take any other reasonable measures that the inspector considers appropriate.

In order to ensure that facility inspections are professional and do not unduly interfere with legitimate life science and other activities involving controlled agents and toxins, a State should promulgate regulations governing the conduct of the inspections and the inspectors, including:

- inspector identification such as a certificate, with the following information:
    - inspector's name and title;
    - inspector's full contact details and photograph;
    - official seal of the Responsible Authority and name of the official that issued the certificate; and
    - expiry date;
- pre-arrival notification to the facility, including the form of the notice with the following information:
    - arrival date and approximate length of inspection;
    - statement of purpose for the inspection;
    - names of the inspection team members and team leader;
    - brief description of the protocol for the inspection (arrival/inspection/departure/report); and
    - full contact details for the office in the Responsible Authority in charge of inspections;
- inspection team pre-briefing on the facility and the host official(s), the controlled agents and toxins that are handled there, the activities that take place there;
- confidentiality agreements governing the conduct of inspectors and their responsibilities for protecting information that comes into their possession as a result of their duties;
- arrival and greeting protocols, or procedures in the absence of the responsible host official (the regulations may specify entry warrant and seizure procedures unique to these inspections or make reference to existing entry warrant and seizure procedures for other types of inspections);
- conduct while on the premises of a facility, including;
    - health and safety matters;
    - emergency procedures;
    - treatment of sensitive business information and research data;
- inspection procedures (also see inspector powers above);
- procedures in the event of suspected non-compliance with national law or regulations or the conditions of a license or permit, including referral for investigation (see Guideline 11); and
- departure protocols.

The regulations should require an inspection report and specify the form of the report with the following information:

- names of inspection team members and team leader;
- date of inspection, start and end time of inspection;
- name of inspected facility and of host official(s) with full contact details;
- description of the inspection, including:
    - the inspection activities;
    - documents reviewed;

- interviews with facility staff; and
- any irregularities between arrival and departure.

The regulations should also require the report to include recommendations to the Responsible Authority, with any suggested security or remedial measures or, in very serious cases, a referral for investigation (see Guideline 11). The regulations should allow the inspected facility to review and prepare a set of comments on the report for the Responsible Authority and specify the format in which these comments must be submitted.

In some cases, the Responsible Authority may decide to issue directions to a facility and require it to meet certain biosecurity standards, ensure that it has an updated security plan in place, or undertake additional measures in order to achieve full compliance with national law and regulations (*Sample Act*, Section 21). These directions could be issued on an *ad hoc* basis, or the regulations could specify the form of the directions with the following information:

- names of inspection team members and team leader;
- date of inspection, start and end time of inspection;
- name of inspected facility and of host official(s) with full contact details;
- the specific security measures to be taken and the timeframe for completion; and
- name and contact details of the official in the Responsible Authority who issued the directions.

Finally, regulations may be necessary to specify:

- the inspection team's budget, including salaries; and
- the composition, administrative functions and organization of the inspection team's secretariat.

11. Investigations

Inspections differ from investigations in a significant way: the Responsible Authority's presumption for an inspection is that a licensed facility is engaged in peaceful, legal activities involving controlled agents or toxins. The Responsible Authority should be authorized to call for an investigation, however, if it has reason to suspect that an entity, facility or individual handling controlled agents or toxins is not complying with national law or regulations, or with the conditions of a license or permit, or if a serious discrepancy was observed during a domestic inspection (Guideline 10)(*Sample Act*, Section 22). Moreover, the law enforcement authorities, in co-operation with the Responsible Authority and BERISS, should be authorized to lead the investigation and turn it into a criminal inquiry if necessary.

A State may need to promulgate regulations to facilitate co-operation among the law enforcement authorities, the Responsible Authority, BERISS, and the office of the prosecutor (or equivalent) in the event of an investigation. A co-operation agreement may be necessary to clarify each party's responsibilities.

This agreement could give law enforcement officials the authorization to lead the investigation, while requiring the Responsible Authority and BERISS to share relevant information, including facility reports and other documentation in the Responsible Authority or BERISS' possession (taking into consideration sensitive business information and research data). The agreement could require the Responsible Authority and BERISS to provide technical assistance during the investigation, which may differ significantly from other types of investigations with which law enforcement officials are more familiar. The agreement could also require BERISS to provide training to a specialized group of law enforcement officers, including:

- general information about bioterrorism;
- the national and international legal frameworks for the prevention and response to biological emergencies, as well as an understanding of the BWC and prohibited activities;
- the correct use of Personal Protection Equipment (PPE);
- other relevant safety procedures;
- specialised investigative techniques such as joint interviews and record-keeping with public health personnel;
- containment;
- biological hazard assessment;
- evidence collection and recovery such as sampling; and
- evidentiary procedures such as chain of custody.

The nature of an investigation involving controlled agents and toxins, or containment and maximum containment environments, will necessarily be different from other types of investigations. For techniques that are common to all of them, the regulations should make reference to an existing code of criminal procedure (or other law or set of regulations governing investigations) to avoid unnecessary duplication. For other techniques, however, the regulations may need to be more specific, particularly in relation to use of PPE in a crime scene; operating in a contained environment and designating it as a crime scene; biohazard assessment; and collecting, securing and maintaining chain of custody for samples and evidence, some of which may be contaminated and infectious. The regulations should also specify how any infectious or contaminated samples or evidence are to be destroyed, once they are no longer needed for an investigation or prosecution (*Sample Act*, Section 23).

Box 10: Investigations

- Interpol's Bioterrorism Prevention Resource Centre (which includes links to materials on, *inter alia*, detection devices, governmental agencies, biocontainment laboratories, decontamination, agents – treatment and surveillance, personal protective equipment): http://www.interpol.int/Crime-areas/Terrorism/CBRNE-programme/Bioterrorism
- Interpol's Bioterrorism Prevention Programme (and *Bioterrorism Incident Pre-Planning & Response Guide*): http://www.interpol.int/Crime-areas/Terrorism/CBRNE-programme/Bioterrorism
- *Biorisk Management - Laboratory Biosecurity Guidance*, WHO, September 2006 (particularly Sections 6.1 and 6.2): http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/