

**A Sample Act for National Implementation of the
1972 Biological and Toxin Weapons Convention and
Related Requirements of
UN Security Council Resolution 1540**



INTRODUCTION

This “Sample Act” was developed to assist countries in drafting legislation to implement the 1972 Biological and Toxin Weapons Convention and the biological weapons-related provisions of UN Security Council Resolution 1540. It is a tool which legislative drafters may freely use, while taking into consideration their country’s legal framework, level of biotechnological development, and other national circumstances.

Legislation to prevent and prohibit biological weapons activities should include offences and penalties for any misuse of biological agents and toxins by non-State actors, as well as provisions enabling a State to effectively regulate legitimate activities. These two approaches together form a robust deterrent against those who would spread fear and panic, injury and death through the intentional release of disease.

Part A of the Sample Act contains a brief introduction and defines terms that have a particular meaning in the legislation. Part B ensures that non-State actors who misuse biological agents and toxins to harm or kill are committing an offence punishable by law. Section 5, in particular, prohibits biological weapons-related activities, terrorist acts involving the intentional release of pathogens, and certain activities involving controlled biological agents and toxins, including internal and international transfers, without proper authorisation. Section 6 ensures that any preparations towards harming or killing with pathogens, including attempts, assistance, financing, or threats are offences punishable by law.

Part C of the Sample Act establishes a robust and comprehensive system, including biosecurity measures, for the prevention of biological weapons proliferation. Sections 9 and 10 provide the building blocks of prevention, through the establishment of lists of biological agents and toxins and equipment and technology, which a State may wish to control through an oversight system. Sections 11 to 14 develop a web of deterrence through licensing of activities related to controlled agents and toxins, notification of internal transfers, import/export permits for international transfers of controlled agents and toxins and equipment and technology, and strict oversight of carriers approved to transport these items.

Part D provides for enforcement and oversight through two proposed agencies in sections 15 and 16. The first is a Responsible Authority, an interagency body responsible for overall policy co-ordination and enforcement of the legislation and any regulations at the national level. The second is the Biological Emergency Response and Investigation Support System (BERISS), which is responsible for co-ordinating the public health and law enforcement response in the event of a natural, accidental or intentional disease outbreak. Part D also requires licensed individuals, entities and carriers to comply with reporting requirements and facility inspections in sections 17 and 18, and provides for law enforcement investigations, by specially trained officers, of suspected violations of the legislation in section 22. Penalties for the offences in Parts B, C and D are found in section 26. Sections 27 and 28 establish jurisdiction and modalities for legal co-operation and assistance with other States and international organisations. Finally, Part E enables the Responsible Authority or appropriate minister to issue any regulations necessary under the legislation.

VERTIC (www.vertic.org) is in a position to assist with the development of national implementing legislation, including in capitals, if requested. This service is free of charge. For further details, please contact Angela Woodward (angela.woodward@vertic.org), Scott Spence (scott.spence@vertic.org) or Rocio Escauriaza (rocio.escauriaza@vertic.org).

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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) assistance project, funded by the governments of the United Kingdom and the Netherlands, has been 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, norms and UN Security Council resolutions and how to implement them.

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May 2009

**An [ACT, STATUTE, ORDINANCE, LAW] to
Implement the 1972 Biological and Toxin Weapons
Convention and Related Requirements of UN Security
Council Resolution 1540**

of [YEAR]

**Adopted by the
[PARLIAMENT, NATIONAL ASSEMBLY] of
[COUNTRY NAME]**

**and Signed into Law on [DATE] by
[HEAD OF GOVERNMENT, HEAD OF STATE]**

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Part A PRELIMINARIES

1. Short title

This [ACT, STATUTE, ORDINANCE, LAW] may be cited as [THE BIOLOGICAL AND TOXIN WEAPONS CONVENTION IMPLEMENTATION [ACT, STATUTE, ORDINANCE, LAW] OF [YEAR]].

2. Purpose

The purpose of this [ACT, STATUTE, ORDINANCE, LAW] is to implement the 1972 Biological and Toxin Weapons Convention and the biological weapons-related provisions of UN Security Council Resolution 1540 by prohibiting any misuse of biological agents and toxins, promoting biosecurity and facilitating [COUNTRY NAME]'s compliance with its international obligations to prevent proliferation of biological weapons. Part B establishes prohibitions on the misuse of biological agents and toxins and related offences. Part C provides for the control of certain biological agents, toxins, equipment and technology and offences for related violations. Part D provides for penalties and enforcement of this [ACT, STATUTE, ORDINANCE, LAW]. Part E provides for regulations under this [ACT, STATUTE, ORDINANCE, LAW].

3. [ACT, STATUTE, ORDINANCE, LAW] to bind the State

This [ACT, STATUTE, ORDINANCE, LAW] is binding on [COUNTRY NAME].

4. Interpretation

(1) In this [ACT, STATUTE, ORDINANCE, LAW] –

- (a) “Biological weapon” means –
 - i. 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;
 - ii. weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;
- (b) “Controlled agents and toxins” and “controlled agents and toxins list” shall have the meaning assigned to each in section 9 of this [ACT, STATUTE, ORDINANCE, LAW];
- (c) “Controlled equipment and technology” and “controlled equipment and technology list” shall have the meaning assigned to each in section 10 of this [ACT, STATUTE, ORDINANCE, LAW];
- (d) “Entity” means any government agency, academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity;
- (e) “Person” means any natural person or, to the extent consistent with internal law as to criminal responsibility, any legal person;
- (f) “Responsible Authority” refers to the body established under section 15 of this [ACT, STATUTE, ORDINANCE, LAW];
- (g) “Territory” means any area within [COUNTRY NAME], or under its jurisdiction or control anywhere.

(2) The [RESPONSIBLE AUTHORITY] may make regulations defining “biological agent”, “toxin”, “equipment” and “technologies” for the purposes of this [ACT, STATUTE, ORDINANCE, LAW].

Part B PROHIBITIONS

5. Misuse of biological agents and toxins

(1) Every person commits an offence who knowingly –

- (a) develops, produces, otherwise acquires, stockpiles or retains any biological weapon, or transfers, directly or indirectly, to anyone, any biological weapon;
- (b) uses any biological weapon;
- (c) engages in preparations to use any biological weapon;
- (d) constructs, acquires or retains any facility intended for the production of biological weapons; or
- (e) weaponises any biological agent or toxin.

(2) Every person commits an offence who intentionally releases biological agents or toxins for the purpose of harming and killing human beings, animals or plants in order to intimidate or coerce a government or civilian population to further political or social objectives.

(3) Every person commits an offence who –

- (a) develops, acquires, manufactures, possesses, transports, transfers or uses controlled agents or toxins –
 - i. without a license granted by the [RESPONSIBLE AUTHORITY] under section 11 of this [ACT, STATUTE, ORDINANCE, LAW],
 - ii. in violation of the conditions of a license granted by the [RESPONSIBLE AUTHORITY] under section 11 of this [ACT, STATUTE, ORDINANCE, LAW], or
 - iii. in violation of any other provision of section 11 of this [ACT, STATUTE, ORDINANCE, LAW];
- (b) transfers controlled agents or toxins within the territory of [COUNTRY NAME] to individuals or entities that have not been granted a license by the [RESPONSIBLE AUTHORITY] under section 12 of this [ACT, STATUTE, ORDINANCE, LAW] or fails to notify the [RESPONSIBLE AUTHORITY] of the transfer;
- (c) imports, exports, re-exports, or transships any controlled agent or toxin or controlled equipment or technology through the territory of [COUNTRY NAME] –
 - i. without a transfer permit granted by the [RESPONSIBLE AUTHORITY] under section 13 of this [ACT, STATUTE, ORDINANCE, LAW], or
 - ii. without an end-user certificate under section 13 of this [ACT, STATUTE, ORDINANCE, LAW];
- (d) fails to transfer controlled agents or toxins, internally or internationally, through an approved carrier or fails to comply with any other provision of section 14;
- (e) constructs, acquires or retains any facility designed or intended for the manufacture of or research on any controlled agent or toxin, except in accordance with this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder or any other [ACT, STATUTE, ORDINANCE, LAW];

- (f) tampers with any facility, package, or containment vessel containing controlled agents or toxins in order to cause their release; or
- (g) diverts or steals controlled agents or toxins from a facility or authorised transport vehicle, or uses or takes control of an authorised transport vehicle containing controlled agents or toxins so as to cause the release of those controlled agents or toxins.

6. Alternative criminal liability

Every person commits an offence who –

- (a) assists, encourages or induces, in any way, anyone to engage in any of the activities prohibited under section 5;
- (b) orders or directs anyone to engage in any of the activities prohibited under section 5;
- (c) attempts to commit any of the offences prohibited under section 5;
- (d) threatens to commit any of the offences prohibited under section 5; or
- (e) acts as an accomplice to or finances any of the activities prohibited under section 5.

7. Official defence barred

It shall not be a defence that a person charged with an offence set forth in this Part acted in an official capacity, under the orders or instructions of a superior, or otherwise in accordance with internal law.

Part C BIOSECURITY

8. Purpose

Part C controls the development, acquisition, manufacture, possession, transport, transfer or use of certain biological agents and toxins, and controls the transfer of certain dual-use biological equipment and technology. The purpose of Part C is to ensure that such agents, toxins, equipment and technology are safely and securely controlled in [COUNTRY NAME]. In particular, this Part and its implementing regulations are intended to prevent theft, loss, diversion, illicit trafficking or other improper release of controlled agents and toxins.

9. Controlled agents and toxins¹

Option 1: [(1) The [RESPONSIBLE AUTHORITY] shall establish and maintain a list of biological agents and toxins that pose a severe threat to public health and safety and national security, based on the following criteria –

- (a) effect of exposure on human, animal, or plant health, or on animal or plant products;
- (b) degree of contagiousness and method of transmission;
- (c) availability and effectiveness of pharmacotherapies and immunisations; and

¹ Two options are provided for preparing a list of the biological agents and toxins to be controlled by the [RESPONSIBLE AUTHORITY] through the licensing, reporting and inspections regimes in this Sample Act: a list based on criteria related to the threat to public health and safety and national security, or a list based on the World Health Organization's four risk group classifications. Examples of existing lists are available on request.

(d) other criteria deemed appropriate, if any, provided that the [RESPONSIBLE AUTHORITY] shall publicly disclose and explain the use of any such criteria.

(2) The biological agents and toxins on the list established under this section shall be referred to as “controlled agents and/or toxins”, and the list of such agents and toxins as the “controlled agents and toxins list”. The controlled agents and toxins list shall be included in the regulations issued pursuant to this section, and shall be periodically reviewed and modified as necessary by the [RESPONSIBLE AUTHORITY].]

Option 2: [(1) The [RESPONSIBLE AUTHORITY] shall establish and maintain a list of biological agents and toxins, based on the World Health Organization’s classification of infective micro-organisms by risk group.² This list, and the guidelines used to establish it, shall be included in the regulations issued pursuant to this section, and shall be periodically reviewed and modified as necessary by the [RESPONSIBLE AUTHORITY].

(2) The biological agents and toxins in Risk Group[s] [1,] [2,] [3,] [and] [4] on the list established under this section shall be referred to as “controlled agents and/or toxins”, and the list of such agents and toxins as the “controlled agents and toxins list”.]

10. Controlled equipment and technology

(1) The [RESPONSIBLE AUTHORITY] shall establish and maintain a list of dual-use biological equipment and technology.³

(2) The dual-use biological equipment and technology on the list established under this section shall be referred to as “controlled equipment and/or technology”, and the list of such equipment and technology as the “controlled equipment and technology list”. The controlled equipment and technology list shall be included under regulations issued pursuant to this section, and shall be periodically reviewed and modified as necessary by the [RESPONSIBLE AUTHORITY].

11. Licensing for controlled agents and toxins

Licensing

(1) Every individual or entity that develops, acquires, manufactures, possesses, transports, transfers or uses controlled agents or toxins shall be in possession of a license from the [RESPONSIBLE AUTHORITY] pursuant to regulations issued under this [ACT, STATUTE, ORDINANCE, LAW]. The regulations shall require that individuals and entities obtaining a

² Laboratory Biosafety Manual (Third Edition), World Health Organization, 2004. The guidelines are: *Risk Group 1* (no or low individual and community risk): A micro-organism 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.

³ Examples of existing lists are available on request.

license under this section have a lawful purpose to develop, acquire, manufacture, possess, transport, transfer or use such controlled agents or toxins.

(2) A license granted under this section shall list each controlled agent or toxin that an individual or entity is authorised to develop, acquire, manufacture, possess, transport, transfer or use.

(3) The regulations issued under this [ACT, STATUTE, ORDINANCE, LAW] shall provide for revocation of a license by the [RESPONSIBLE AUTHORITY] in appropriate cases, including any violation of this [ACT, STATUTE, ORDINANCE, LAW].

(4) A license shall not be granted by the [RESPONSIBLE AUTHORITY] to those prohibited individuals and entities listed in the regulations issued under this [ACT, STATUTE, ORDINANCE, LAW].

Exemptions from licensing

(5) An exemption from a license under this section shall only be granted by the [RESPONSIBLE AUTHORITY] for public health or agricultural emergencies, evidentiary purposes, or for products licensed under food, drug, cosmetics, insecticide or similar laws.

Entity licenses and Compliance Officer

(6) An application for a license by an entity shall include information on ownership or control of the entity. Any entity seeking a license under this section shall also, as a condition of approval, identify, authorise and notify to the [RESPONSIBLE AUTHORITY] an individual in each of its facilities as a “Compliance Officer” for purposes of ensuring compliance with this [ACT, STATUTE, ORDINANCE, LAW] and the regulations issued hereunder. The Compliance Officer must possess adequate authority to act on behalf of the facility respecting compliance with this [ACT, STATUTE, ORDINANCE, LAW] and the regulations issued hereunder. The entity shall liaise with its facilities’ Compliance Officers and the [RESPONSIBLE AUTHORITY] for the purposes of enforcement of this [ACT, STATUTE, ORDINANCE, LAW] and shall have such other responsibilities as the regulations may provide.

(7) Any entity licensed under this section shall only allow access to controlled agents or toxins by individuals who are also licensed under this section to develop, acquire, manufacture, possess, transport, transfer or use controlled agents or toxins.

Notification of facilities

(8) The entity shall notify all of its facilities that develop, acquire, manufacture, possess, transport, transfer or use controlled agents or toxins, and licensed individuals working at those facilities, to the [RESPONSIBLE AUTHORITY]. The facilities that are notified to the [RESPONSIBLE AUTHORITY] shall be known as “notified facilities”.

Entity licenses, biosecurity and biosafety

(9) (a) Every entity seeking a license under this section shall, as a condition of approval, confirm that its notified facilities comply with the biosecurity regulations issued pursuant to this [ACT, STATUTE, ORDINANCE, LAW]⁴, to prevent access to controlled agents or toxins by unlicensed individuals. The regulations shall specify physical protection measures, including physical and personnel security plans, for facilities where controlled agents or toxins are developed, acquired, manufactured, possessed, transported, transferred or used. The regulations

⁴ States may wish to consider preparing these regulations in line with the Laboratory Biosafety Manual (Third Edition), World Health Organization, 2004.

shall require personnel security background checks to ensure the reliability of individuals working in facilities where controlled agents or toxins are developed, acquired, manufactured, possessed, transported, transferred or used. Requirements for physical and personnel security shall be commensurate with the risk the controlled agents and toxins pose to public health and safety.

(b) Every entity seeking a license under this section shall also, as a condition of approval, confirm that its notified facilities comply with the biosafety regulations issued pursuant to this [ACT, STATUTE, ORDINANCE, LAW]⁵, to prevent unintentional exposure to controlled agents and toxins, or their accidental release.

Record-keeping by the [RESPONSIBLE AUTHORITY]

(10) The [RESPONSIBLE AUTHORITY] shall maintain an accurate and current record of all licensed individuals and entities and notified facilities under this section, including the names and locations of the licensed individuals and entities and notified facilities, and information on the controlled agents or toxins each individual or entity is licensed to develop, acquire, manufacture, possess, transport, transfer or use.

Notice of theft, loss or release

(11) Individuals and entities (and their notified facilities) licensed under this section shall immediately notify the [RESPONSIBLE AUTHORITY], the [APPROPRIATE LAW ENFORCEMENT AGENCY] and the [[COUNTRY NAME] Biological Emergency Response and Investigation Support System (BERISS)] of the theft, loss or release of controlled agents or toxins. Licensed entities may establish procedures for the notification of theft, loss or release by their notified facilities.

Risk assessment for activities involving non-controlled agents and toxins

(12) Subsection (1) notwithstanding, any individual, entity or facility that develops, acquires, manufactures, possesses, transports, transfers or uses non-controlled agents or toxins shall complete a risk assessment, in the manner prescribed in the regulations issued under this [ACT, STATUTE, ORDINANCE, LAW], for each activity that it undertakes which it reasonably believes may pose a threat to public health and safety and national security. This risk assessment shall be submitted to the [RESPONSIBLE AUTHORITY] within the time frame specified in the regulations.

12. Internal transfer controls for controlled agents and toxins

(1) Controlled agents and toxins shall only be transferred within the territory of [COUNTRY NAME] among individuals and entities (and their notified facilities) licensed pursuant to this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder.

(2) All proposed transfers of controlled agents or toxins within the territory of [COUNTRY NAME] are subject to advance notification to the [RESPONSIBLE AUTHORITY] in accordance with the regulations issued under this [ACT, STATUTE, ORDINANCE, LAW].

(3) Regulations issued by the [RESPONSIBLE AUTHORITY] shall specify additional technical and security requirements for transfer, including measures to track controlled agents and toxins

⁵ States may wish to consider preparing these regulations in line with the Laboratory Biosafety Manual (Third Edition), World Health Organization, 2004.

and to confirm receipt of the transfer by the transferee, such that strict accountability for controlled agents and toxins is maintained at all times.

13. International transfer controls

Import, export, re-export, and transshipment of controlled agents and toxins and controlled equipment and technology

(1) Every individual or entity that imports, exports, re-exports, or transships any controlled agent or toxin or controlled equipment or technology through the territory of [COUNTRY NAME] shall be in possession of a permit from the [RESPONSIBLE AUTHORITY OR NATIONAL IMPORT/EXPORT CONTROL AUTHORITY].

(2) The [RESPONSIBLE AUTHORITY OR NATIONAL IMPORT/EXPORT CONTROL AUTHORITY] shall issue regulations establishing the requirements and procedures to obtain a transfers permit for controlled agents or toxins or controlled equipment or technology.

(3) If the [RESPONSIBLE AUTHORITY] has reason to believe or suspect that an imported, exported, re-exported, or transhipped non-controlled agent or toxin or non-controlled equipment or technology might be used for purposes prohibited by this [ACT, STATUTE, ORDINANCE, LAW], the [RESPONSIBLE AUTHORITY] may obtain an injunction from appropriate judicial authorities to prevent the import, export, re-export, or transshipment.

Export procedures

(4) The [RESPONSIBLE AUTHORITY OR NATIONAL IMPORT/EXPORT CONTROL AUTHORITY] shall adopt procedures to ensure that controlled agents or toxins or controlled equipment or technology are only exported to individuals, entities or facilities in another State that are similarly regulated in respect of controlled agents or toxins or controlled equipment or technology.

(5) The procedures in subsection (4) shall include a requirement for an end-use certificate which shall contain, at a minimum –

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

Transit

(6) The [RESPONSIBLE AUTHORITY OR NATIONAL IMPORT/EXPORT CONTROL AUTHORITY] shall issue regulations establishing the requirements and procedures for the transit of controlled agents or toxins or controlled equipment or technology through the territory of [COUNTRY NAME].

14. Transportation of controlled agents and toxins

Transfers by approved carriers only

(1) Internal and international transfers of controlled agents and toxins under sections 12 and 13 shall only be undertaken by carriers approved by the [MINISTRY OF TRANSPORTATION OR RESPONSIBLE AUTHORITY] under subsection (2).

Approved carriers

(2) The [MINISTRY OF TRANSPORTATION OR RESPONSIBLE AUTHORITY] shall maintain a roster of carriers approved to transport controlled agents and toxins internally and internationally. The roster shall only include those carriers that have demonstrated to the [MINISTRY OF TRANSPORTATION OR RESPONSIBLE AUTHORITY] that they comply with best practices for packaging and labelling; shipment tracking; and safety and security measures for their personnel, vehicles and facilities.

Transport guidelines

(3) Internal and international transportation of controlled agents and toxins shall be conducted in accordance with the hazardous material transport guidelines and packaging and labelling requirements issued by the [MINISTRY OF TRANSPORTATION] and any regulations issued by the [RESPONSIBLE AUTHORITY] under this [ACT, STATUTE, ORDINANCE, LAW]. Every carrier that imports, exports, re-exports, transships or transits controlled agents or toxins through the territory of [COUNTRY NAME] shall also comply with all applicable international regulations for the shipment of hazardous materials.

Notification of theft, loss or release of controlled agents or toxins

(4) Carriers approved under this section to transport controlled agents and toxins internally or internationally shall immediately notify the [RESPONSIBLE AUTHORITY], the [APPROPRIATE LAW ENFORCEMENT AGENCY] and the [[COUNTRY NAME] BIOLOGICAL EMERGENCY RESPONSE AND INVESTIGATION SUPPORT SYSTEM (BERISS)] of the theft, loss or release of controlled agents or toxins.

Part D ENFORCEMENT

15. Establishment, mandate and enforcement powers of the [RESPONSIBLE AUTHORITY]

Establishment

(1) This section establishes a [RESPONSIBLE AUTHORITY] for the enforcement of this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder.

Composition⁶

(2) The [RESPONSIBLE AUTHORITY] shall consist of –

- (a) a representative from the [Prime Minister's, Head of Government's] office, who shall also serve as the Chairperson of the [RESPONSIBLE AUTHORITY];
- (b) a representative from the Ministry of Foreign Affairs;

⁶ This list is only illustrative and should be tailored according to the country's constitutional and statutory regimes, circumstances, needs, etc.

- (c) a representative from the Ministry of Justice;
- (d) a representative from the Office of the Attorney-General;
- (e) a representative from the Ministry of Industry;
- (f) a representative from the Ministry of Environment;
- (g) a representative from the Ministry of Health;
- (h) a representative from the Ministry of Agriculture;
- (i) a representative from the Ministry of the Interior;
- (j) a representative from the Ministry of Transportation;
- (k) a representative from the [NATIONAL FORENSIC SCIENCE LABORATORY];
- (l) representatives from the [NATIONAL BORDER CONTROL AUTHORITIES (CUSTOMS, PORT AUTHORITIES)] ;
- (m) a representative from the [COUNTRY NAME] Chamber of Commerce; and
- (n) a representative from a biological industry association in [COUNTRY NAME].

Functions and duties of the [RESPONSIBLE AUTHORITY]

(3) The [RESPONSIBLE AUTHORITY] shall perform the following functions in a transparent and reviewable manner –

- (a) To be the [RESPONSIBLE AUTHORITY] for [COUNTRY NAME];
- (b) To supervise and monitor the enforcement of this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder;
- (c) To issue licenses and permits under this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder;
- (d) To provide international organisations and other States with relevant data and information in fulfilment of [COUNTRY NAME]'s international obligations;
- (e) To facilitate inspections under this [ACT, STATUTE, ORDINANCE, LAW];
- (f) To prepare guidelines for the conduct of biological research for lawful purposes;
- (g) To establish, liaise with and review the activities of the Biological Emergency Response and Investigation Support System (BERISS);
- (h) To liaise with the equivalent of the [RESPONSIBLE AUTHORITY] in other States;
- (i) To perform any other tasks assigned to it by appropriate authorities;
- (j) To report annually to the [PARLIAMENT, NATIONAL ASSEMBLY] on the activities of the Responsible Authority and the Biological Emergency Response and Investigation Support System (BERISS); and
- (k) To advise the [PRIME MINISTER, HEAD OF GOVERNMENT] on matters relevant to this [ACT, STATUTE, ORDINANCE, LAW], and to provide any information which the Prime Minister or other appropriate authorities may require.

(4) The [RESPONSIBLE AUTHORITY] may appoint a task force to advise it on any matter relating to this [ACT, STATUTE, ORDINANCE, LAW].

16. Establishment of [[COUNTRY NAME] Biological Emergency Response and Investigation Support System (BERISS)]

Establishment

(1) The [RESPONSIBLE AUTHORITY] shall establish a [BIOLOGICAL EMERGENCY RESPONSE AND INVESTIGATION SUPPORT SYSTEM (BERISS)] to facilitate communication and response to biological emergencies impacting human, animal or plant health, and to assist the [APPROPRIATE LAW ENFORCEMENT AGENCY] with investigations of biological incidents.

Composition of the BERISS co-ordination team

(2) BERISS shall be managed and co-ordinated by a team consisting of –

- (a) a representative from the [RESPONSIBLE AUTHORITY] who shall act as a liaison between the [RESPONSIBLE AUTHORITY] and BERISS;
- (b) a representative from the [MINISTRY OF HEALTH OR FOOD AND DRUG SAFETY AGENCY];
- (c) a representative from the Ministry of Agriculture;
- (d) a representative from the Ministry of Environment;
- (e) an emergency medicine practitioner;
- (f) a law enforcement officer from the [APPROPRIATE LAW ENFORCEMENT AGENCY] trained to respond to biological emergencies;
- (g) representatives from the [NATIONAL BORDER CONTROL AUTHORITIES (CUSTOMS, PORT AUTHORITIES)];
- (h) an epidemiologist;
- (i) a veterinary scientist;
- (j) a media relations specialist;
- (k) specialists in bacterial, toxicological, viral, Rickettsial, and prion diseases; and
- (l) any other relevant expert(s) as BERISS sees fit.

(3) Members of the BERISS co-ordination team shall be required to receive appropriate security clearances enabling them to work with national security, law enforcement and public health officers.

Functions and duties

(4) The BERISS co-ordination team shall carry out the following duties in a transparent and reviewable manner –

- (a) manage and guide the national and local response to emergencies associated with biological agents and toxins in co-ordination with the [RESPONSIBLE AUTHORITY];
- (b) in co-ordination with other governmental agencies, as appropriate, establish public health and agricultural surveillance and reporting systems with respect to the development, acquisition, manufacture, possession, transport, transfer or use of controlled agents and toxins;
- (c) ensure the effectiveness of a public emergency announcement system;
- (d) ensure the proper training and equipping of law enforcement officers from the [APPROPRIATE LAW ENFORCEMENT AGENCY], emergency/first responders and hospitals in responding to emergencies involving biological agents and toxins;
- (e) create threat-based medical and public health detection strategies to detect and determine outbreaks associated with biological agents and toxins;
- (f) receive and review classified biological threat intelligence;
- (g) receive and review public health information;
- (h) collect, maintain, and present evidence needed for review of forensic epidemiological investigations and for prosecutions;
- (i) transmit data and information regarding biological emergencies and incidents to the [RESPONSIBLE AUTHORITY]; and
- (j) undertake other activities regarding preparation for and response to emergencies involving biological agents and toxins, including co-operation with law enforcement officers from the [APPROPRIATE LAW ENFORCEMENT AGENCY].

Regulations

(5) The [RESPONSIBLE AUTHORITY] shall be authorised to issue regulations providing for the establishment and operation of BERISS.

17. Record-keeping and reporting and related offences

Purpose

(1) The purpose of this section is to ensure that –

- (a) controlled agents and toxins are only developed, acquired, manufactured, possessed, transported, transferred, or used for lawful purposes; and
- (b) facilities in which controlled agents and toxins are developed, acquired, manufactured, possessed, transported, transferred, or used are physically secure.

(2) Any power under this section may be exercised only for the purposes in subsection (1).

Record-keeping and providing information

(3) Every individual, entity and carrier subject to this [ACT, STATUTE, ORDINANCE, LAW] and the regulations issued hereunder shall –

- (a) Keep and maintain the data, information and documents specified by the regulations at the individual, entity or carrier's place of business, or at such other place as may be designated by the [RESPONSIBLE AUTHORITY], in the manner and for the period that is specified by the regulations;
- (b) Prepare reports from such data, information and documents as may be specified by the regulations; and
- (c) Provide such reports to the [RESPONSIBLE AUTHORITY] or any other authority specified by the regulations, at such times and in a form specified by the regulations.

Notice for disclosure of information

(4) The [RESPONSIBLE AUTHORITY] may send a notice to any individual, entity or carrier whom the [RESPONSIBLE AUTHORITY] believes on reasonable grounds has data, information or documents relevant to the enforcement of this [ACT, STATUTE, ORDINANCE, LAW], requesting the individual, entity or carrier to provide the data, information or documents to the [RESPONSIBLE AUTHORITY].

(5) An individual, entity or carrier who receives a notice referred to in subsection (4) shall provide the requested data, information and documents that are under the individual, entity or carrier's care or control to the [RESPONSIBLE AUTHORITY] in the form and within the time specified in the notice.

Transmission of information by the [RESPONSIBLE AUTHORITY]

(6) The [RESPONSIBLE AUTHORITY] shall be authorised to transmit relevant data and information obtained under this [ACT, STATUTE, ORDINANCE, LAW] to other States and international organizations.

Offences

(7) Every person commits an offence who fails to provide any data, information or document to the [RESPONSIBLE AUTHORITY], or who makes a false or misleading statement in any data, information, document or report prepared pursuant to this section.

(8) Every person commits an offence who omits any matter, knowing that the omission makes any data, information, document or report prepared pursuant to this section false or misleading.

(9) Every person commits an offence who obtains data, information, documents or reports pursuant to this [ACT, STATUTE, ORDINANCE, LAW] or any regulations issued hereunder and, without written consent, communicates the data, information, documents or reports to any other person in any form, except –

- (a) for the purpose of the enforcement or application of this [ACT, STATUTE, ORDINANCE, LAW] or any regulations issued hereunder, including criminal investigations and intelligence assessments;
- (b) pursuant to an international obligation of [COUNTRY NAME]; or
- (c) to the extent that the data, information, documents or reports are required to be disclosed or communicated in the interest of public safety.

18. Inspections

Purpose

(1) Under this section, the [RESPONSIBLE AUTHORITY] is authorised to facilitate inspections of the individuals, entities (and their facilities) and carriers subject to regulation under this [ACT, STATUTE, ORDINANCE, LAW] to ensure their compliance with this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder, including compliance with all applicable biosecurity measures.

Designation of inspectors

(2) The [RESPONSIBLE AUTHORITY] may designate persons or classes of persons⁷ as inspectors for the purpose of the enforcement of this [ACT, STATUTE, ORDINANCE, LAW], and may set conditions for the conduct of inspection activities.

Carrying out of inspections

(3) An inspector may, with the consent of the person in control of any premises or under a warrant, enter the premises and exercise any power under subsection (4) to ensure –

- (a) that the provisions of this [ACT, STATUTE, ORDINANCE, LAW] and any regulations issued hereunder have been or are being complied with; or
- (b) that the conditions applicable to a license or permit issued under sections 11 or 13 have been or are being complied with by the license or permit holder.

Powers

(4) An inspector carrying out an inspection may –

- (a) search any premises;
- (b) operate any photographic or video-recording equipment anywhere in or around the premises provided safety regulations in force at the premises permit doing so;
- (c) require the attendance of and question any person whom the inspector considers will be able to assist in the inspection;

⁷ States may wish to consider designating officials already responsible for biosafety and biosecurity in laboratories and other facilities, as well as law enforcement officers trained in biosecurity and biological emergency response, as members of an inspection team for the purposes of this section.

- (d) inspect or examine, take samples of, detain or remove any substance or item considered relevant by the inspector to the enforcement of this [ACT, STATUTE, ORDINANCE, LAW];
- (e) 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, STATUTE, ORDINANCE, LAW];
- (f) 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;
- (g) 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;
- (h) reproduce or cause to be reproduced any record from the data, in the form of a printout or other intelligible output, and remove the printout or other output for examination or copying;
- (i) have operated any equipment, including electronic equipment located at the premises;
- (j) be accompanied by an expert, as appropriate, chosen by the inspector and authorised by the [RESPONSIBLE AUTHORITY]; and
- (k) require that any person in control of the premises take any other reasonable measures that the inspector considers appropriate.

(5) A power referred to in subsection (4) may only be exercised in a manner that the person in control of the premises believes, on reasonable grounds, to be in accordance with safety procedures applicable at the premises.

Inspection warrants

(6) An inspector may apply for a warrant where the consent of the person in control of any premises cannot be obtained or is refused under subsection (3).

(7) A [JUSTICE OF THE PEACE, MAGISTRATE] may issue a warrant authorising the inspector named in the warrant to enter the premises, subject to any conditions that may be specified in the warrant, if he is satisfied that there are reasonable grounds for believing that –

- (a) entry to the premises is necessary for the purpose under subsection (1); and
- (b) entry to the premises cannot be obtained, has been refused or there are reasonable grounds to believe that entry will be refused.

19. Obligations of inspectors

Identification certificates

(1) An inspector, expert, or a representative of the [RESPONSIBLE AUTHORITY] shall be given a certificate of designation.

(2) An inspector, expert, or a representative of the [RESPONSIBLE AUTHORITY] on entering any premises under this [ACT, STATUTE, ORDINANCE, LAW] shall produce the certificate of designation at the request of the person in control of the premises, at any reasonable time.

Notice of entry and seizure

(3) Every inspector shall, as soon as is practicable after completing the inspection, give the person in control of the premises a written notice stating that the premises have been entered, if, at any time between the time of entry of any premises to be inspected and the time the inspection is completed, there is no person appearing to be in control of the premises, and specify the following matters –

- (a) the time and date of entry;
- (b) the circumstances and purpose of entry; and
- (c) the name of every person entering.

(4) Every inspector shall provide copies of any documents under subsection (3) to the [RESPONSIBLE AUTHORITY].

(5) Every inspector shall, where applicable, have a warrant with him or her and produce it if required to do so, and where any thing is seized, give the person in control of the premises a written inventory of all things so seized.

Inspector report and referral for investigation

(6) Every inspector shall provide a report of their inspection to the [RESPONSIBLE AUTHORITY] and describe any suspected non-compliance with this [ACT, STATUTE, ORDINANCE, LAW] or the regulations issued hereunder. The [RESPONSIBLE AUTHORITY] may refer cases of suspected non-compliance to the [APPROPRIATE LAW ENFORCEMENT AGENCY] for investigation under section 22.

20. Obligations of persons in control of inspected premises and related offences

Assistance to inspectors

(1) The person in control of a premises entered under section 18, and every person present in the premises, shall give an inspector and any expert accompanying an inspector all reasonable assistance to enable the inspector and any accompanying expert to perform his duties, and shall furnish the inspector with any information related to the administration of this [ACT, STATUTE, ORDINANCE, LAW] that the inspector reasonably requests.

Written directions

(2) The [RESPONSIBLE AUTHORITY] may, by notice in writing, issue directions to any person for the purpose of facilitating an inspection under section 18.

Offences

(3) Every person commits an offence who fails to comply with any reasonable direction given by the [RESPONSIBLE AUTHORITY] under subsection (2).

(4) Every person commits an offence who obstructs, hinders, resists or deceives or makes any false or misleading statement to any inspector, or expert accompanying any inspector, who is exercising any function contemplated or any power provided for in section 18.

(5) Every person commits an offence who removes, alters or interferes in any way with any thing seized under section 18, except with the authorisation of an inspector.

21. Directions requiring security measures and related offence

(1) The [RESPONSIBLE AUTHORITY] may give directions in writing to an individual, or in the case of a facility, a Compliance Officer, requiring him to –

- (a) take such measures to ensure the security of controlled agents or toxins or controlled equipment or technology;

- (b) review and update any security plans; and
- (c) take any other measures that the [RESPONSIBLE AUTHORITY] may reasonably require.

(2) Where the [RESPONSIBLE AUTHORITY] has reasonable grounds for believing that adequate measures to ensure the security of controlled agents or toxins or controlled equipment or technology kept or used in any relevant premises are not being taken and are unlikely to be taken, it may give directions in writing to the individual or, in the case of a facility, the Compliance Officer, requiring him to destroy or dispose of the items. The directions shall specify how and by when the items must be destroyed or disposed of.

Offence

(3) Every person commits an offence who fails to comply with directions given by the [RESPONSIBLE AUTHORITY] under subsections (1) or (2).

22. Investigations

Purpose

(1) The purpose of this section is to promote co-operation among the [APPROPRIATE LAW ENFORCEMENT AGENCY], the [RESPONSIBLE AUTHORITY], and BERISS in investigating suspected violations of this [ACT, STATUTE, ORDINANCE, LAW].

Investigations

(2) In the event of a suspected violation of this [ACT, STATUTE, ORDINANCE, LAW], the [APPROPRIATE LAW ENFORCEMENT AGENCY] shall be authorised to lead an investigation of the suspected violation in co-ordination with the [RESPONSIBLE AUTHORITY] and BERISS.

(3) Any records kept pursuant to this [ACT, STATUTE, ORDINANCE, LAW] by the [RESPONSIBLE AUTHORITY], BERISS, an individual, entity, or carrier shall be made available to law enforcement officers with the [APPROPRIATE LAW ENFORCEMENT AGENCY] investigating suspected violations of this [ACT, STATUTE, ORDINANCE, LAW].

(4) Any samples collected during inspections or investigations shall be analysed in accordance with the regulations issued under this [ACT, STATUTE, ORDINANCE, LAW] or any other [ACT, STATUTE, ORDINANCE, LAW], and the results of the analysis may be used as evidence in judicial proceedings.

Training

(5) In order to be prepared for investigations under this section, law enforcement officers from the [APPROPRIATE LAW ENFORCEMENT AGENCY] shall receive training from BERISS in responding to biological emergencies, including –

- (a) general information about bioterrorism;
- (b) the national and international legal frameworks for the prevention and response to biological emergencies, as well as an understanding of the Biological and Toxin Weapons Convention and prohibited activities involving biological agents and toxins;
- (c) the proper use of Personal Protection Equipment;
- (d) other relevant safety procedures;
- (e) specialised investigative techniques such as joint interviews and record-keeping with public health personnel;

- (f) containment;
- (g) biological hazard assessment;
- (h) evidence collection and recovery such as sampling; and
- (i) evidentiary procedures such as chain of custody.

23. Seizure, forfeiture and destruction

(1) The [RESPONSIBLE AUTHORITY OR APPROPRIATE LAW ENFORCEMENT AGENCY] may seek a warrant authorising –

- (a) the seizure of any biological agent or toxin or equipment or technology associated with any activity prohibited under this [ACT, STATUTE, ORDINANCE, LAW]; or
- (b) the freezing or seizure of any funds associated with any activity prohibited under this [ACT, STATUTE, ORDINANCE, LAW].

(2) In exigent circumstances, seizure of any biological agent or toxin or equipment or technology associated with any activity prohibited under this [ACT, STATUTE, ORDINANCE, LAW], may be authorised by the [RESPONSIBLE AUTHORITY] without a warrant.

(3) Property seized under subsections (1) and (2) shall be forfeited to the Government after notice to potential claimants and an opportunity for a hearing. [At such hearing, the Government shall bear the burden of proof by a preponderance of the evidence that the seized property pertains to conduct prohibited under this [ACT, STATUTE, ORDINANCE, LAW]].

(4) The [RESPONSIBLE AUTHORITY] may provide for the destruction or other appropriate disposition of any biological agent or toxin or equipment or technology seized and forfeited under this section.

24. Injunctions

The [RESPONSIBLE AUTHORITY] may obtain an injunction from the appropriate judicial authorities against the conduct prohibited under Part B.

25. Continuing offence

[Where an offence under this [ACT, STATUTE, ORDINANCE, LAW] is committed or continued on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which the offence is committed or continued.]

26. Criminal and civil penalties

Criminal liability of individuals and entities

(1) In addition to any penalties that may apply under other provisions of law, including for violations of the criminal, licensing, transfer control laws of [COUNTRY NAME], the penalties in subsections (3)-(8) shall apply for violations by individuals and entities of Parts B, C and D of this [ACT, STATUTE, ORDINANCE, LAW] and the regulations issued hereunder.

Liability of entity directors, managers, secretaries and other officers

(2) Where an offence under this [ACT, STATUTE, ORDINANCE, LAW] is committed by an entity and proven to have been committed with the consent and connivance of, or to be

attributable to any negligence on the part of, any director, manager, secretary or other similar officer of the entity, or any person who was purporting to act in such capacity, he as well as the entity shall be guilty of that offence and shall also be liable to be proceeded against and punished pursuant to this section.

Misuse of biological agents and toxins

(3) Every person who commits an offence under section 5 of this [ACT, STATUTE, ORDINANCE, LAW] is guilty of an offence and liable upon conviction to –

- (a) in the case of an individual, imprisonment for a term not exceeding [PERIOD] years or to a fine not exceeding [AMOUNT] or both; or
- (b) in the case of an individual, where the offence results in death, [LIFE IMPRISONMENT]; or
- (c) in the case of an entity, a fine not exceeding [AMOUNT].

(4) Every person who commits an offence under section 6 of this [ACT, STATUTE, ORDINANCE, LAW] is guilty of an offence and liable upon conviction to –

- (a) in the case of an individual, imprisonment for a term not exceeding [PERIOD] years or to a fine not exceeding [AMOUNT] or both; or
- (b) in the case of an individual, where the offence results in death, [LIFE IMPRISONMENT]; or
- (c) in the case of an entity, a fine not exceeding [AMOUNT].

(5) In the event of a criminal prosecution under subsection (3) or (4), there shall be a *prima facie* presumption that an individual or entity in possession of a license or permit duly granted under section 11 or 13 has a lawful purpose for developing, acquiring, manufacturing, possessing, transporting, transferring or using the controlled agents or toxins listed in the license or permit.

Record-keeping and reporting

(6) Every person who commits an offence under section 17 of this [ACT, STATUTE, ORDINANCE, LAW] is guilty of an offence and liable upon conviction to –

- (a) in the case of an individual, imprisonment for a term not exceeding [PERIOD] years or to a fine not exceeding [AMOUNT] or both; or
- (b) in the case of an entity, a fine not exceeding [AMOUNT].

Obligations of persons in control of inspected premises

(7) Every person who commits an offence under section 20 of this [ACT, STATUTE, ORDINANCE, LAW] is guilty of an offence and liable upon conviction to –

- (a) in the case of an individual, imprisonment for a term not exceeding [PERIOD] years or to a fine not exceeding [AMOUNT] or both; or
- (b) in the case of an entity, a fine not exceeding [AMOUNT].

Directions requiring security measures

(8) Every person who commits an offence under section 21 of this [ACT, STATUTE, ORDINANCE, LAW] is guilty of an offence and liable upon conviction to –

- (a) in the case of an individual, imprisonment for a term not exceeding [PERIOD] years or to a fine not exceeding [AMOUNT] or both; or

(b) in the case of an entity, a fine not exceeding [AMOUNT].

27. Application

(1) This [ACT, STATUTE, ORDINANCE, LAW] shall extend –

- (a) to acts or omissions prohibited under this [ACT, STATUTE, ORDINANCE, LAW], which are committed by any natural or legal person in the territory of [COUNTRY NAME];
- (b) to acts or omissions prohibited under this [ACT, STATUTE, ORDINANCE, LAW], which are committed by a[n] [COUNTRY NAME] national outside the territory of [COUNTRY NAME];
- (c) to acts or omissions prohibited by this [ACT, STATUTE, ORDINANCE, LAW], which are committed on board [COUNTRY NAME] sea vessels and aircraft;
- (d) to acts or omissions prohibited by this [ACT, STATUTE, ORDINANCE, LAW], which are committed by a stateless person whose habitual residence is the territory of [COUNTRY NAME];
- (e) to acts or omissions prohibited by this [ACT, STATUTE, ORDINANCE, LAW], which are committed with the intent to harm [COUNTRY NAME] or its nationals or to compel [COUNTRY NAME] to do or abstain from doing any act; or
- (f) to acts or omissions prohibited by this [ACT, STATUTE, ORDINANCE, LAW], in which the victim of the offence is a national of [COUNTRY NAME].

(2) For the purposes of subsection (1)(c), “[COUNTRY NAME] sea vessels and aircraft” shall mean sea vessels and aircraft registered in [COUNTRY NAME] or belonging to, or in the possession of, [COUNTRY NAME].

28. Legal co-operation and assistance

(1) The offences set forth in Part B of this [ACT, STATUTE, ORDINANCE, LAW] shall be deemed to be included as extraditable offences in any extradition treaty existing between [COUNTRY NAME] and other States.

(2) Subsection (1) notwithstanding, the competent authorities of [COUNTRY NAME] for crime prevention, criminal proceedings, and implementation of this [ACT, STATUTE, ORDINANCE, LAW] may collaborate with other competent State authorities and international organizations, and co-ordinate their actions to the extent required by the implementation of this [ACT, STATUTE, ORDINANCE, LAW] or of the equivalent foreign statute(s), subject to the other State authorities or international organizations being bound to official secrecy.

(3) The competent authorities of [COUNTRY NAME] may request other State authorities and international organizations, under subsection (2), to provide relevant data or information. The competent authorities of [COUNTRY NAME] are authorised to receive data or information concerning, *inter alia* –

- (a) the development, acquisition, manufacture, possession, transport, transfer or use of biological agents and toxins, whether controlled or non-controlled;
- (b) dual-use biological equipment and technology, whether controlled or non-controlled; or
- (c) persons involved with items under subsections (a) and (b).

(4) If a State has entered into the appropriate reciprocity agreement with [COUNTRY NAME], the competent authorities of [COUNTRY NAME] may provide, on their own initiative or on request, the data or information described in subsection (3) to that State so long as the other competent State authority provides assurances that such data or information shall –

- (a) only be utilised for purposes consistent with this [ACT, STATUTE, ORDINANCE, LAW] and
- (b) only be used in criminal proceedings on the condition that they are obtained in accordance with those provisions governing international judicial cooperation.

(5) The competent authorities of [COUNTRY NAME] may provide the data or information described in subsection (3) to international organizations if the conditions set forth in subsection (4) are fulfilled, in which case the requirement for a reciprocity agreement is waived.

(6) None of the offences in Part B of this [ACT, STATUTE, ORDINANCE, LAW] shall be regarded, for the purposes of extradition or legal co-operation and assistance under this section, as a political offence or as an offence connected with a political offence or as an offence inspired by political motives.

Part E REGULATIONS

29. Regulations

In addition to the regulations required elsewhere in this [ACT, STATUTE, ORDINANCE, LAW], the [RESPONSIBLE AUTHORITY], or a Minister who has authority in relation to this [ACT, STATUTE, ORDINANCE, LAW], may make such other regulations as are necessary to carry out the purposes and provisions of this [ACT, STATUTE, ORDINANCE, LAW].
