

# **Model Law**

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



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This Model Law is a revision 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, published in 2012.

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# Introduction

## The National Implementation Measures Programme

VERTIC's National Implementation Measures (NIM) Programme, established in 2008, provides tailored assistance to interested states for adherence to and implementation of international instruments, including those on chemical, biological, nuclear and radiological weapons and the security of related materials. The NIM Programme provides cost-free assistance through awareness-raising, legal analysis and legislative drafting assistance to interested states.

For over a decade, the NIM Programme has been engaged in systematic analysis and drafting of states' implementing legislation for the 1972 Biological Weapons Convention (BWC). Through our engagement with over 145 states worldwide and our participation in diplomatic and technical BWC-related processes, we have developed a unique understanding of states' approaches to implementing the Convention and of what constitutes effective practice.

One of the primary activities of the NIM Programme is assistance with drafting implementing legislation for the BWC and biological weapons-related provisions of related instruments. This usually follows legislative analysis of existing legislation to identify gaps, using our BWC-legislation survey template, which can be found on VERTIC's website at <https://www.vertic.org/programmes/nim/biological-weapons-and-materials/legislative-analysis-tool/>.

In our drafting activities, which include reviewing draft legislation but also working with states in developing the first legislative drafts, the NIM team uses a number of tools. These include examples of other countries' legislation, which can be found on our BWC legislation database, and relevant guidance developed by other organisations. Our BWC legislation database can be found on VERTIC's website at <https://www.vertic.org/programmes/nim/biological-weapons-and-materials/bwc-legislation-database/>.

A number of other resources may be helpful to read alongside this Model Law to provide further context, examples and guidance for both legislation and regulations. These include the United Nations Office for Disarmament Affairs (UNODA) 'Guide to Implementing the Biological Weapons Convention', which VERTIC contributed to (available on UNODA's website at <https://www.un.org/disarmament/guide-to-implementing-the-biological-weapons-convention/>). VERTIC's Regulatory Guidelines National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540 may also be helpful to consult alongside the Model Law. More information can be found on VERTIC's website at <https://www.vertic.org/programmes/nim/biological-weapons-and-materials/legislation-drafting-tools/>.

## The Model Law

This Model Law 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 can be used to identify all the relevant measures that should be included in national legislation to give effect to the BWC and related provisions of UNSCR 1540. It can further be used during the legislative drafting process. As there is no “one size fits all” approach for the drafting of national implementing legislation, each state should determine the type of implementing measures it requires in accordance with its constitutional processes, legal tradition, existing legal framework, activities in the field of bioscience and other national circumstances. The Model Law is therefore intended to provide a useful basis to draft BWC implementing legislation and can be used to draft new legislation, or amend existing laws and/or regulations.

The provisions of the Model Law have been drafted as a reference for the development of primary legislation. Although some states may also find it useful for drafting or amending subsidiary legislation or other regulatory instruments, such as regulations, decrees, resolutions or orders, depending on the national legal system, the Model Law does not contain the full range of detailed technical provisions that are typically included in such subsidiary instruments. For ease of reference, the Model Law refers generally to such subsidiary regulatory instruments as “regulations”.

## **Structure and content of the Model Law**

As a baseline, legislation to prevent and prohibit biological and toxin 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 system against any misuse of biological agents and toxins. The Model Law follows this approach.

The Model Law includes in Chapter 1 general provisions on the title, purpose and scope of the Law, while also defining the terms that have a particular meaning in the legislation. Chapter 2 focuses on offences and penalties for biological and toxin weapons and unauthorised activities with biological agents and toxins, as well as procedures for criminal investigations and measures to facilitate international cooperation on related matters.

Chapter 3 provides for the establishment or designation of the national authority(ies) responsible for overall policy coordination and enforcement of the legislation and any regulations at the national level. Chapter 4 establishes a system of control of peaceful activities with biological agents and toxins. It provides the building blocks of prevention, through the establishment of a list of biological agents and toxins as well as equipment and technology, which a state may wish to control through an oversight system. It also provides for the licensing of activities related to listed biological agents and toxins, including international transfers of listed biological agents and toxins and equipment and technology, as well as related obligations of licensees, including measures for inspection and enforcement.

Chapter 5 sets out fundamental biosafety and biosecurity measures for peaceful use of the life sciences, while Chapter 6 focuses on coordinating the public health and law enforcement preparedness and response in the event of a biological incident. Lastly, Chapter 7 deals with final provisions, including formalities such as entry into force, legislative amendments and transitional measures.

The provisions of the Model Law should be tailored to each state’s specific context and chosen approach for BWC implementation. For instance, states wishing to develop comprehensive legislation for implementing the BWC will find a useful reference in all the provisions of the Model Law, while specific chapters may be particularly useful for states wishing to develop or amend legislation on certain elements of BWC implementation, such as the criminalisation of prohibited activities or the establishment of a biosafety and biosecurity legal framework.



# Acknowledgement and liabilities

The Model Law is a revision of VERTIC's 2012 Sample Act for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540, which was the product of hard work from a number of current and former staff of the National Implementation Measures Programme. The development of the Model Law was conducted by Ms Yasemin Balci, Dr Sonia Drobysz, Ms Suzanna Khoshabi, and Mr Thomas Brown. The team wishes to acknowledge and recognise the major contributions of Ms Fanny Tonos Paniagua, senior legal consultant, for her valuable input and insightful feedback. VERTIC wishes to thank the Ministry of Foreign Affairs of Norway for their financial support in developing this version. The views expressed by VERTIC do not necessarily reflect theirs. Although every care has been taken to prepare this Model Law, VERTIC hereby disclaims any liability or responsibility arising from their use in any way. VERTIC would be grateful for any errors or omissions that are brought to our attention.



Norwegian Ministry  
of Foreign Affairs



# The Model Law

## CHAPTER 1 GENERAL PROVISIONS

### Section/Article<sup>1</sup> 1: Title

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This [Act/Law] may be referred to as the Biological and Toxin Weapons Convention [Act/Law] of [year].

OR

[Act/Law] on the prohibition of biological and toxin weapons and peaceful use of biological agents and toxins [year]<sup>2</sup>.

#### Box 1 – Title of the Act/Law

Section/Article 1 reflects the legislative practice existing in many states to include a reference to the title or short title of the Act/Law in the text of the legislation.

Depending on the intended purpose, scope and content of the legislation, some states may prefer to take a different approach for the title, moving away from the weapons aspect.

For example, “The Biological Agents and Toxins Act/Law” or “The Biosafety and Biosecurity Act/Law”.

For examples of laws concerning biological weapons in BWC States Parties, see VERTIC’s BWC Legislation Database.

### Section/Article 2: Purpose

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The purpose of this [Act/Law] is to implement the 1972 Biological and Toxin Weapons Convention (BWC) and the biological weapons-related provisions of UN Security Council Resolution 1540; to prohibit biological and toxin weapons as well as any misuse of biological agents and toxins; and to regulate the safe and secure handling of biological agents and toxins for peaceful purposes.

#### Box 2 – Purpose of the Act/Law

Depending on the intended purpose, scope and content of the legislation, as reflected in the title chosen by the state (see Box 1), a tailored purpose will also be necessary.

For example, the purpose of a law entitled “The Pathogens and Toxins Act/Law” may be “to provide bio-safety and biosecurity measures with respect to pathogens and toxins”.

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- 1 States should choose the appropriate wording for relevant terms such as ‘Section’ or ‘Article’ and ‘Act’ or ‘Law’, according to their legal traditions.
  - 2 In some states, the title of the Act includes the short title of the treaty it is implementing (e.g. the Netherlands’ “Implementing Law of the Biological Weapons Convention”, while in other states, the title of the act only refers to the subject matter (e.g. Botswana’s “Biological and Toxin Weapons (Prohibition) Act, 2018”).

## Section/Article 3: Scope

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- (1) This [Act/Law] shall apply to any activities involving a listed biological agent or toxin, equipment and technology conducted in [State].
- (2) This [Act/Law] shall not apply to activities regulated by the [Title of Act/Law].

### Box 3 – Scope of the Act/Law

Section/Article 3 reflects the legislative practice existing in many states to include a scope provision, which is particularly relevant when establishing a regime for regulatory control, as it serves to determine the scope of application of the control system over the handling of biological agents and toxins for peaceful purposes (see Chapters 4 and 5). States wishing to exclude specific activities governed by other regulatory regimes from the scope of application of the Act/Law may also do so under such a provision.

## Section/Article 4: Definitions

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In this [Act/Law],

- (1) **“Activities involving listed biological agents and toxins”** means the development, production, acquisition, storage, possession, transport, transfer, use, disposal, import, export, re-export, transit or trans-shipment of a listed biological agent or toxin;
- (2) **“Activities involving listed equipment, technology and software”** means the import, export, re-export, transit or trans-shipment of a listed equipment, technology or software;
- (3) **“Biological agent”** means any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material that may be able to provoke infection, allergy, toxicity or other adverse effects in humans, animals, or plants;<sup>3</sup>
- (4) **“Biological or toxin weapon”<sup>4</sup>** means together or separately:
  - (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;
- (5) **“Biosafety”** means the containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins or their accidental release;<sup>5</sup>
- (6) **“Biosecurity”** means the principles, technologies and practices that are implemented for the protection, control and accountability of biological agents and toxins and/or the equipment, skills and data related to their handling, to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release;<sup>6</sup>

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3 This definition has been drawn from the *International Organization for Standardization’s ISO 35001:2019(E) on Biorisk management for laboratories and other related organisations*, section 3.13. An alternative definition can be found in the *World Health Organization’s Laboratory Biosafety Manual, 4<sup>th</sup> edition, 2020*, in the Glossary of Terms: “A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants”.

4 See Article 1 of the BWC. The phrase “together, or separately” has been drawn from the 1993 Chemical Weapons Convention to make explicit that subsections (a) and (b) can both independently and jointly constitute a biological weapon.

5 This definition has been drawn with modifications from the *World Health Organization’s Laboratory Biosafety Manual, 4<sup>th</sup> edition, 2020*, page x. An alternative definition can be found in the *International Organization for Standardization’s ISO 35001:2019(E) on Biorisk management for laboratories and other related organisations*, page 4: “practices and controls that reduce the risk of unintentional exposure or release of biological materials”.

6 This definition has been drawn with modifications from the *World Health Organization’s Laboratory Biosafety Manual, 4<sup>th</sup> edition, 2020*, page xi. An alternative definition can be found in the *International Organization for Standardization’s ISO 35001:2019(E) on Biorisk management for laboratories and other related organisations*, page 4: “practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials”.

- (7) **“Broker”** means the negotiation or arrangement of transactions for the purchase, sale or supply of goods/listed materials from a third state to any other third state or the selling or buying of goods/ listed materials that are located in third state for their transfer to another third state;<sup>7</sup>
- (8) **“BWC” or “Biological Weapons Convention”** means the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction adhered to by [State] through [title and reference of instrument] of [date];
- (9) **“Dual-use items”** means items, including equipment, technology and software, which can be used for both civil and military purposes, including items which can be used for the design, development, production or use of biological weapons or their means of delivery;<sup>8</sup>
- (10) **“Dual-use research”** means biological research conducted for peaceful purposes that has the potential to produce knowledge, information, methods, products or technologies that could also be intentionally misused for harmful purposes;<sup>9</sup>
- (11) **“Export”** means to take state goods out of the physical jurisdiction or customs territory of [State];<sup>10</sup>
- (12) **“Import”** means to bring into the physical jurisdiction or customs territory of [State];<sup>11</sup>
- (13) **“International transfer”** means the import, export, re-export, transit or trans-shipment of listed biological agents and toxins, equipment, technology or software;
- (14) **“Listed biological agents or toxins”** means the biological agents and toxins listed in accordance with Section/Article 13;
- (15) **“Listed biological equipment, technology and software”** means the equipment and related technology and software listed in accordance with Section/Article 14;
- (16) **“National authority”** means the institution designated at the national level responsible for coordinating national implementation of the BWC and this [Act/Law] in accordance with Section/Article 11;
- (17) **“Person”** means any natural person or legal person;<sup>12</sup>
- (18) **“Re-export”** means non-state goods which are taken out of the physical jurisdiction or customs territory of [State];<sup>13</sup>
- (19) **“Software”** means a collection of one or more programmes fixed in any tangible medium of expression;<sup>14</sup>
- (20) **“Technology”** means specific information necessary for the development, production or use of biological agents and toxins, biological equipment and software;<sup>15</sup>

.....

- 7 This definition has been drawn with modifications from Article 2, Section 7 of the *European Union Regulation 2021/821*.
- 8 This definition has been drawn with modifications from Article 2, Section 1 of the *European Union Regulation 2021/821*. An alternative definition can be found in the the *World Health Organization’s Biorisk manual: Laboratory Biosecurity Guidance, 2006*, page iv: “Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also to harmful misuse and peaceful activities”.
- 9 This definition has been drawn with modifications from the *World Health Organization’s Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research, 2022*, page xx: “Research conducted for peaceful and beneficial purposes that has the potential to produce knowledge, information, methods, products or technologies that could also be intentionally misused to endanger the health of humans, nonhuman animals, plants and agriculture, and the environment. In the context of this framework, it refers to work in the life sciences, but the principles are also applicable to other scientific fields.”
- 10 This definition has been drawn with modifications from the *European Union Customs Code (UCC)*, Article 269.
- 11 This definition has been drawn with modifications from definitions found in export control laws and regulations of various states.
- 12 In this Model Law, a “natural” person refers to individuals and a “legal” person refers to companies, corporations and similar bodies. This definition of “person” may also include entities conducting activities with biological agents and toxins or biological equipment, software or technology which require a licence. Whether legal persons (e.g. companies, charities etc.) in addition to natural persons (i.e. individuals) can be held criminally liable depends on a state’s national legal framework.
- 13 This definition has been drawn with modifications from the *European Union Customs Code (UCC)*, Article 270.
- 14 This definition has been drawn with modifications from the *European Union Regulation 2021/821, Annex 1, Definitions of Terms Used in This Annex*.
- 15 This definition has been drawn with modifications from *European Union Regulation 2021/821, Annex 1, Definitions of Terms Used in This Annex*. The full definition includes “information [that] takes the form of ‘technical data’ or ‘technical assistance’”.

- (21) **“Territory”** means any area within [State], or under its jurisdiction or control anywhere;
- (22) **“Toxin”** means a substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals or plants;<sup>16</sup>
- (23) **“Trans-shipment”** means the unloading of goods from one ship and its loading into another to complete a journey to a further destination;<sup>17</sup>
- (24) **“Transfer”** means import, export, re-export, transit, trans-shipment, movement within [State] or change of ownership;
- (25) **“Transit”** means transport of non-state items entering and passing through the customs territory of [State] with a destination outside the customs territory of [State].<sup>18</sup>

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16 This definition has been drawn from the *International Organization for Standardization’s ISO 35001:2019(E) on Biorisk management for laboratories and other related organisations*, section 3.15.

17 This definition has been drawn with modifications from the *Glossary for transport statistics, 5<sup>th</sup> edition, 2019 co-published by the European Union, the United Nations and the International Transport Forum at the OECD*, page 100.

18 This definition has been drawn with modifications from Article 2, Section 11 of the *European Union Regulation 2021/82*.

## CHAPTER 2

### CRIMINAL PROVISIONS

#### Section/Article 5: Offences related to biological weapons

- (1) A person who commits any of the following acts will be punished upon conviction with [penalties in the form of imprisonment and/or fines]:
- (a) develops, produces, otherwise acquires, stockpiles, possesses or transports a biological or toxin weapon;
  - (b) transfers, directly or indirectly, a biological or toxin weapon;
  - (c) uses a biological or toxin weapon;
  - (d) engages in military preparations to use a biological or toxin weapon; or
  - (e) constructs, acquires or retains a facility intended for the production of biological or toxin weapons.

#### Box 4 – Biological weapons-related criminal offences: international instruments

This Model Law focuses on the implementation of the BWC and the biological weapons-related provisions of UN Security Council Resolution 1540. However, a number of other international instruments contain obligations related to biological weapons that a state may wish to include as offences in their national legislation. These include:

- the 2010 Convention on the Suppression of Unlawful Acts Relating to International Civil Aviation (the Beijing Convention);
- the 2005 Convention for the Suppression of Unlawful Acts Against the Safety of Maritime Navigation (as amended by the 2005 Protocol);
- the 2005 Protocol for the Suppression of Unlawful Acts against the Safety of Fixed Platforms Located on the Continental Shelf (as amended by the 2005 Protocol to the Protocol);
- the 1997 International Convention for the Suppression of Terrorist Bombings; the 1998 Rome Statute of the International Criminal Court; and
- United Security Council Resolution 1540 (2004)

A state may have chosen to deal with their obligations arising from these instruments in their criminal code or counter-terrorism legislation. If so, they may wish to either amend these to include specific biological weapons-related terrorism offences or consider including terrorism offences related to biological weapons in their BWC-implementing law.

- (2) Section/Article 5(1) extends to conduct outside the territory of [State] committed:
- (a) by a person who is a national of [State];
  - (b) by a stateless person or resident whose habitual residence is in the territory of [State];
  - (c) against a national of [State]; or
  - (d) with the intent to harm [State] or its nationals or to compel [State] to do or abstain from doing any act.

#### Section/Article 6. Offences related to listed biological agents and toxins

A person who commits any of the following acts will be punished upon conviction with [penalties in the form of imprisonment and/or fines]:

- (1) develops, produces, acquires, stores, possesses, transports, transfers, uses or disposes of a listed biological agent or toxin without a licence or in violation of the terms of a licence; or

- (2) imports, exports, re-exports, transits or trans-ships listed biological agents and toxins without a licence or in violation of the terms of a licence; or
- (3) brokers the import, export, re-export, transit or trans-shipment of listed biological agents and toxins without a licence or in violation of the terms of a licence; or
- (4) fails to comply with any other provision of this [Act/Law] or any regulations issued hereunder; or
- (5) constructs, acquires or retains a facility designed or intended for the conduct of activities involving a listed biological agent or toxin, except in accordance with this [Act/Law] and any regulations issued hereunder or any other [Act/Law]; or
- (6) diverts, takes control of or tampers with a facility, vehicle or package containing listed biological agents or toxins.

## **Section/Article 7: Offences related to listed biological equipment and technology**

A person who commits any of the following acts will be punished upon conviction with [penalties in the form of imprisonment and/or fines]:

- (1) imports, exports, re-exports, transits or transships listed biological equipment or technology without a licence or in violation of the terms of a licence; or
- (2) brokers the import, export, re-export, transit or trans-shipment of listed biological equipment or technology without a licence or in violation of the terms of a licence.

### **Box 5 – Criminal offences: National approaches**

There are a number of different approaches to including offences in national legislation. In addition to incorporating offences such as those outlined in Chapter 2 in a biological weapons-specific law, states may also – or additionally – choose to include offences such as those in Section/Article 5 in their criminal code, and offences such as those in Sections/Articles 6 and 7 in specific laws relating to biosafety or biosecurity.

## **Section/Article 8: Participatory offences**

A person who commits any of the following acts will be punished upon conviction with [penalties in the form of imprisonment and/or fines] –

- (1) attempts;
- (2) assists, encourages or induces;
- (3) organises, orders or directs;
- (4) acts as an accomplice to;
- (5) threatens; or
- (6) finances;

any of the activities prohibited in articles/sections 5, 6 and 7.

### **Box 6 – Participatory offences**

The participatory offences outlined in Section/Article 8 may already be covered in a state's criminal code. States should nevertheless ensure that all such offences are covered, whether they appear generally in the criminal code or specifically in biological weapons-related legislation.

## Section/Article 9: Criminal investigations

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### Box 7 – Criminal procedure legislation

Measures facilitating criminal investigations and international cooperation on related matters may already be included in existing legislation, for example, in a state's criminal procedure code and laws on mutual legal assistance and extradition.

A state should therefore assess its existing laws in order to ensure that criminal investigations of suspected biological incidents and international cooperation on related matters are specifically addressed in legislation. If not, states may wish to consider amending the law in question to ensure that offences involving biological agents and toxins are covered by its scope.

### *Investigations*

- (1) In the event of a suspected offence under this [Act/Law], the [law enforcement agency] shall be authorised to lead an investigation of the suspected offence in co-ordination with other relevant national authorities.

### *Seizure, forfeiture and destruction*

- (2) The [responsible authority or 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/Law]; or
  - (b) the freezing or seizure of any funds associated with any activity prohibited under this [Act/Law].
- (3) In exigent circumstances, seizure of any biological agent or toxin or equipment or technology associated with any activity prohibited under this [Act/Law] may be authorised by the [responsible authority] without a warrant.
- (4) Property seized under subsections (1) and (2) shall be forfeited to the State after notice to potential claimants and an opportunity for a hearing.
- (5) The [responsible authority or law enforcement agency] 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.

### *Injunctions*

- (6) The [responsible authority] may obtain an injunction from the appropriate judicial authorities against the conduct prohibited under this Chapter.

## Section/Article 10: International legal cooperation

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### *Extraditable offences*

- (1) The offences set forth in Section/Article 5 of this [Act/Law] shall be deemed to be included as extraditable offences in any extradition treaty existing between [State] and other states.

### *Collaboration and coordination*

- (2) Subsection (1) notwithstanding, the competent authorities of [State] for crime prevention, criminal proceedings, and implementation of this [Act/Law] may collaborate with other competent state authorities and international organisations, and coordinate their actions to the extent required by the implementation of this [Act/Law] or of the equivalent foreign statute(s), subject to the other state authorities or international organisations being bound to official secrecy.



### ***Data and information-sharing between states***

- (3) The competent authorities of [State] may request other state authorities and international organisations, under subsection (2), to provide relevant data or information. The competent authorities of [State] are authorised to receive data or information concerning, *inter alia* –
- (a) activities involving biological agents and toxins, whether listed or non-listed;
  - (b) dual-use biological equipment and technology, whether listed or non-listed; or
  - (c) persons involved with items under subsections (a) and (b).

### ***Data and information-sharing assurances***

- (4) If a state has entered into the appropriate reciprocity agreement with [State], the competent authorities of [State] 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/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.

### ***Data and information-sharing between states and international organisations***

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

### ***No political offence exception***

- (6) None of the offences in Section/Article 5 of this [Act/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.

## CHAPTER 3

### NATIONAL AUTHORITY FOR THE BWC

#### Section/Article 11: Establishment/Designation of the National Authority

- (1) The [responsible authority] is hereby [designated/established] as the National Authority for the BWC.

##### Box 8 – National Authority for the BWC

A state can decide whether to designate an existing entity as the **national authority** for overseeing implementation of the BWC or to create a new one specifically for this function. A national authority for the BWC could be established or designated within a government ministry or department, as an inter-ministerial body or as an independent governmental authority.<sup>19</sup>

Whether a single existing department is designated as the National Authority or a single new department or a combination of departments and entities are established as the National Authority, it is important to include a wide range of government departments, ministries and other agencies. This is because these have functions and expertise that are highly relevant to BWC implementation. A state may wish to consider representing the following departments, ministries or agencies in the work of a National Authority for the BWC:

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

Section/Article 12 lists the main functions associated with BWC implementation. If the approach chosen by the state is to create or designate a multisectoral body as the National Authority, the focus of the legal provisions would then normally be to provide the basis for effective interinstitutional coordination, including a delineation of responsibilities, with relevant details to be provided through regulations.

#### Section/Article 12: Functions of the [National Authority for the BWC and/or responsible authority(ies)]

The [National Authority for the BWC and/or the responsible authority(ies)] shall perform the following functions for the enforcement of this [Act/Law] and any regulations issued hereunder:

- (1) Liaise with other states and relevant international organisations on matters related to the implementation of the BWC;
- (2) Prepare and submit relevant reports for the implementation of the BWC [including Confidence Building Measures];
- (3) Supervise and monitor the enforcement of this [Act/Law] and any regulations issued hereunder;
- (4) Issue, renew, suspend and revoke licences and permits under this [Act/Law] and any regulations issued hereunder;

<sup>19</sup> For further detail on establishing a BWC National Authority, see VERTIC's Fact Sheet on [National Authority for the Biological Weapons Convention](#).

- (5) Facilitate inspections under this [Act/Law];
- (6) Prepare guidelines for the conduct of biological research for peaceful purposes;
- (7) Conduct and periodically review national assessments of biological threats and risks;
- (8) Develop procedures to prepare, detect, respond and investigate biological emergencies and other biological incidents;
- (9) Ensure interagency coordination for all matters relating to the implementation of this [Act/Law];
- (10) Promote and facilitate biosafety and biosecurity training;
- (11) Liaise with relevant other [responsible authority(ies)] in other states;
- (12) Report to the [Parliament / National Assembly] on the activities of the [responsible authority(ies)];
- (13) Propose and develop policies and advise the [Head of State] on matters relevant to this [Act/Law], and to provide any information which the [Head of State] or other appropriate authorities may require;
- (14) Cooperate with other states or international organisations on scientific and technological cooperation in the peaceful uses of biological agents and toxins and international public, animal and plant health and disease control; and
- (15) Perform any other tasks assigned to it by appropriate authorities.

#### **Box 9 – Scientific and technological cooperation**

Scientific and technological cooperation on the peaceful uses of biological agents and toxins could include activities such as the transfer and exchange of information, training of personnel and transfer of materials and equipment, bio-sciences and genetic engineering.

Cooperation for the purposes of international public, animal and plant health and disease control could include activities such as the exchange of information on public, animal, plant health; national epidemiological surveillance and epizootic surveillance; bilateral, regional and multilateral assistance; development of frameworks for disease surveillance in humans, animals and plants; and programmes for effective responses at the national, bilateral, regional and multilateral levels.

## CHAPTER 4

# CONTROL REGIME FOR LISTED BIOLOGICAL AGENTS, EQUIPMENT, TECHNOLOGY AND SOFTWARE

### Section/Article 13: Listed biological agents and toxins

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- (1) The [responsible authority] shall establish a list of biological agents and toxins subject to control under this [Act/Law] [to be issued in regulations].
- (2) The [responsible authority] shall periodically review and update the list of biological agents and toxins as necessary.

#### Box 10 – Establishing control lists for biological agents and toxins

UN Security Council Resolution 1540 (2004) operative paragraph 6 recognises the utility of effective national control lists of biological weapons-related materials to implement the resolution, including the requirements to establish domestic controls over such materials. WHO guidance on biosafety and biosecurity acknowledges that countries may wish to adopt a list-based approach to which national biosafety and biosecurity regulations will apply.<sup>20</sup>

Lists of biological agents and toxins are better placed in regulations rather than directly in legislation. This will allow for such lists to be more easily modified in order to stay up to date with scientific and technological developments.

Lists are normally established on the basis of a classification of biological agents and toxins into risk groups based on each biological agent's characteristics, epidemiological profile, the likelihood it will cause damage to human, animals and plants, and the consequences if infection were to occur.

Some countries have also taken the approach of referring to international or regional control lists, such as the Australia Group common control lists.

For more information on establishing a list of biological agents and toxins and on which agents and toxins should normally be included, see VERTIC's Regulatory Guidelines.

### Section/Article 14. Listed biological equipment, technology and software

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- (1) The [responsible authority] shall establish a list of biological equipment, technology and software subject to control under this [Act/Law] [to be issued in regulations].
- (2) The [responsible authority] shall periodically review and update the list of biological equipment, technology and software.

#### Box 11 – Establishing control lists for equipment, technology and software

Lists of biological equipment, technology and software are better placed in regulations rather than directly in legislation. This will allow for such lists to be more easily modified in order to stay up to date with scientific and technological developments.

It should be noted that such lists are for the purpose of controlling **international** transfers of biological equipment, technology and software. Control of domestic transfers of these dual-use items is an onerous administrative burden and is therefore not recommended.

Measures controlling international transfers of such items may also already exist in different national legislation, for example, in laws controlling strategic or sensitive goods. A state should therefore assess its existing laws in order to check that, if such a law exists, biological equipment, technology and software

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<sup>20</sup> See, for example, the *World Health Organization Laboratory Biosafety Manual, 4th edition, page 93*.

and all relevant activities (e.g., export, re-export, transit, trans-shipment) are covered by it. If not, states may wish to consider amending the law in question to ensure that these items and activities are covered by its scope.

States may choose to develop their own national lists of listed biological equipment, technology and software, or to refer to existing international or regional control lists (such as those elaborated by the Australia Group or the Wassenaar Arrangement).

For more information on establishing a list of biological equipment, technology and software, see VERTIC's Regulatory Guidelines.

## Section/Article 15: Licensing

### Box 12 – Licensing: national approaches

A national system of control over activities involving listed biological agents and toxins, equipment, technology and software typically includes a licensing system.

Under such a licensing (or permit) system, persons conducting activities with listed biological agents and toxins, equipment, technology and software need to obtain a licence from the relevant licensing authority. The state should establish: types of licences; requirements for granting a licence; the application procedure; any licensing exemptions and declaration requirements; grounds and appeal procedures for denial or revocation of a licence; enforcement measures as well as offences and penalties for engagement in activities without a licence or in violation of applicable legal provisions and the terms of the licence.

Alternatively, some states prefer to choose a declaration system, under which persons conducting activities with listed biological agents and toxins, equipment, technology and software need to submit a declaration notifying the responsible authority. The state may decide if notification is required in advance, or if afterwards, a time limit within which a declaration should be submitted. Conditions for submitting a declaration, such as a requirement to submit a risk management plan for any work with listed materials, can be included in subsequent regulations.

In many states, there is a combination of regulatory instruments, following a risk-based approach. This Model Law focuses on the licensing system, while providing the option of establishing a declaration system for exempted activities.

### *Licensing requirement*

- (1) A person that conducts activities involving listed biological weapons and toxins, equipment, technology and software must be in possession of a licence from the [responsible authority] pursuant to the provisions of this [Act/Law] and the regulations issued hereunder prior to the conduct of such activities, unless an exemption applies.
- (2) A person applying for a licence under this section must have a prophylactic, protective or other peaceful purpose to develop, acquire, manufacture, possess, store, transport, transfer, use or dispose of listed biological agents or toxins.
- (3) A person applying for a licence under this section must provide information about the facility or facilities in which they develop, acquire, manufacture, possess, store, transport, transfer, use or dispose of listed biological agents or toxins, and the facility or facilities' location, to the [responsible authority].
- (4) A licence must not be granted by the [responsible authority] to those prohibited persons listed in the regulations issued under this [Act/Law].
- (5) A licence granted under this section will list each listed biological agent or toxin that the licensee is licenced to develop, acquire, manufacture, possess, store, transport, transfer, use or dispose of.

### ***Exemptions from licensing***

- (6) Licensing exemptions may be granted by the [responsible authority] for public health or agricultural emergencies, evidentiary purposes, for products licensed under food, drug, cosmetics, insecticide or similar laws or for categories of listed biological agents and toxins based on an evaluation of the risk.

### ***Declarations***

- (7) Exempted activities may be subject to declaration requirements as provided in regulations issued under this [Act/Law].
- (8) A person required to submit a declaration under subsection (7) shall do so [in advance / within a specified time limit] to the [responsible authority] detailing the specified activity, purpose and quantities of listed biological agents or toxins, pursuant to regulations issued under this [Act/Law].

### ***Licence procedures***

- (9) Procedures and requirements for licence applications, for the renewal, suspension and revocation of licences and for declarations shall be established by regulations issued under this [Act/Law].

### ***Transfers between licensees only***

- (10) Listed biological agents and toxins shall be transferred among licensees only and pursuant to the requirements established under this [Act/Law].

## **Section/Article 16: International transfer controls**

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### ***Catch-all clause***

- (1) If the [responsible authority] has reason to believe or suspect that an imported, exported, re-exported, transhipped or transited non-listed biological agent or toxin or any non-listed biological equipment, technology or software might be used for purposes prohibited by this [Act/Law], the [responsible authority] may:
  - (a) Require a licence from the person that imports, exports, re-exports, tranships or transits any non-listed biological agent or toxin or any listed biological equipment, technology or software through the territory of [State]; or
  - (b) Obtain an injunction from the [appropriate judicial authorities] to prevent the import, export, trans-shipment or transit].

### ***Export procedures***

- (2) The [responsible authority] shall adopt procedures to ensure that listed biological agents or toxins or listed biological equipment, technology or software are only exported to individuals, entities or facilities in another state that are similarly regulated in respect of listed biological agents or toxins or listed equipment or technology.

### ***End-use certificate***

- (3) The procedures in subsection (2) shall include a requirement for an end-use certificate which shall contain, at a minimum –
  - (a) A statement that the listed biological agents or toxins or listed biological equipment, technology or software will only be used for lawful purposes;
  - (b) A statement that the listed biological agents or toxins or listed biological equipment, technology or software will not be re-transferred;

- (c) A description of the listed biological agents or toxins or listed biological equipment, technology or software to be transferred;
- (d) The end-use of the listed biological agents or toxins or listed biological equipment, technology or software to be transferred; and
- (e) The name(s) and location(s) of the end-user(s) and any intermediaries.

## Section/Article 17: Inspections

### Box 13: Inspections, investigations and enforcement

An oversight system typically includes a national system of inspections of facilities handling listed biological agents and toxins. If there are very few facilities handling listed biological agents or toxins in its territory, a state may require the responsible authority(ies) 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(ies) would have to confirm, however, that these inspectors have the necessary expertise and are qualified to operate in containment and maximum containment environments, or else facilitate the appropriate training for the small number of inspectors that would be required.

Inspections differ from investigations in a significant way: the presumption for an inspection is that a licensee is engaged in peaceful, legal activities involving listed biological agents or toxins. An investigation will be called for, however, if there is reason to suspect that an entity handling listed biological agents or toxins is not complying with national law or regulations, or with the terms of a licence or permit, or if a serious discrepancy was observed during an inspection. The responsible authorities should be authorised to conduct the investigation, take enforcement measures to remedy any non-compliance and initiate a criminal investigation if necessary (see Section/Article 9).

### *Designation of inspectors*

- (1) The [responsible authority] may designate persons or classes of persons as inspectors for the enforcement of this [Act/Law], and may set conditions for the conduct of inspectors.

### *Carrying out of inspections*

- (2) An inspector may enter the premises and exercise any power to ensure –
  - (a) that the provisions of this [Act/Law] and any regulations issued hereunder have been or are being complied with; or
  - (b) that the terms applicable to a licence or permit issued under Section/Article 15 have been or are being complied with by the licensee.

### Box 14 – Inspection powers

Depending on the national legal system and relevant legislation, powers of inspectors may be listed in varying degrees of detail in national legislation and may be further specified through regulations. Such powers may include searching premises, questioning staff, using photographic or video-recording equipment, taking samples and/or asking for copies of documentation, amongst others.

### *Obligations of persons in control of inspected premises*

- (4) The person in control of a premises entered under Section/Article 17(2), and every person present on the premises, shall grant access to inspectors conducting inspections under this section and comply with any other obligations provided in this [Act/Law] or in the regulations issued hereunder.

## Section/Article 18: Enforcement

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### *Determination of non-compliance*

- (1) In the event of suspected non-compliance by the licensee with the provisions of this [Act/Law], any regulations issued hereunder, or the terms of a licence, the [responsible authority] shall examine the results of inspections, the explanations provided by the licensee and other relevant aspects to determine if there has been a non-compliance.

#### **Box 15 – Administrative enforcement**

Administrative enforcement refers to the remedial and punitive measures that may be imposed by the responsible authority in the event of non-compliance, which are different from the criminal sanctions that may be imposed by a court upon conviction when the non-compliance constitutes a punishable offence under national legislation. Administrative enforcement may take place in the absence of, or in parallel to, criminal investigations and prosecution. The nature of administrative enforcement measures, as well as related procedures and appeals against such decisions, will depend on the national legal system of each state. In some states, a detailed list of non-compliance situations and applicable administrative sanctions, commensurate with the seriousness of the violation, may be found in the legislation or in its implementing regulations or in relevant administrative laws.

### *Enforcement measures*

- (2) In the event of non-compliance by the licensee determined in accordance with subsection (1), the [responsible authority] shall take the necessary enforcement measures [in accordance with the relevant legislation] and may, commensurate with the seriousness of the violation:
  - (a) Issue a written warning and instruct the licensee to remedy the non-compliance within a specified period;
  - (b) Request the licensee to suspend the activity until the non-compliance has been remedied;
  - (c) Impose an administrative fine to the licensee;
  - (d) Amend, suspend or revoke the licence.

### *Obligation of licensee*

- (3) Every licensee shall take the necessary steps to remedy the non-compliance as requested by the [responsible authority] in accordance with subsection (2).

### *Enforcement procedures*

- (4) Procedures for the determination of non-compliance and the taking of enforcement measures in accordance with subsections (1) and (2) shall be established through regulations.

### *Criminal investigations*

- (5) In the event of non-compliance determined in accordance with subsection (1) the [responsible authority] may:
  - (a) Request the [law enforcement agency(ies)] to initiate a criminal investigation according to the terms of Section/Article 9;
  - (b) Request warrants or injunctions to be issued according to the terms of Section/Article 9.



## CHAPTER 5

# BIOSECURITY AND BIOSAFETY

### Box 16 – Biosecurity, biosafety and dual-use research

Detailed biosecurity and biosafety measures may be better placed in regulations than in legislation, as these can be more easily adapted to respond to scientific and technological developments and related security requirements. When drafting such regulations, states may wish to consult the World Health Organization's *Laboratory Biosafety Manual (Fourth Edition)*, 2020.

In addition, responsible use of the life sciences is becoming an increasingly important aspect of biosafety and biosecurity oversight. Given the need to stay up to date with scientific and technological developments, as well as the need to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for peaceful purposes, states may also wish to establish in relevant regulations measures to ensure responsible use of the life sciences.

When drafting such regulations, states may find it helpful to consult the World Health Organization's *Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research*, 2022.

### Section/Article 19: Biosecurity and biosafety

- (1) Every licensee under Section/Article 15 shall take measures to prevent unauthorised access to listed biological agents or toxins, in line with the provisions of this [Act/Law], the regulations issued hereunder and the terms of a licence.
- (2) Every licensee under Section/Article 15 shall take measures to prevent unintentional exposure to listed biological agents and toxins, or their accidental release, in line with the provisions of this [Act/Law], the regulations issued hereunder<sup>21</sup> and the terms of a licence.

### Box 17 – Control over non-listed biological agents and toxins

National biosafety and biosecurity frameworks typically focus on activities involving listed biological agents and toxins. Activities involving non-listed biological agents and toxins may however also pose biosafety and biosecurity risks and may further raise concerns of dual use. To address this matter, states may choose to expand the scope of application of the oversight framework and provide for the option of requiring risk assessments for some of those activities as well. Encouraging the adoption of codes of conduct for responsible research in life sciences may also be useful in this context.

### Section/Article 20: Biosecurity and biosafety measures

- (1) Every licensee under Section/Article 15 shall comply with biosafety and biosecurity regulations issued pursuant to this [Act/Law], which may detail measures including but not limited to:
  - (a) facility design, receipt and storage of biological agents and toxins, decontamination and waste management and disposal of biological agents and toxins;
  - (b) occupational health measures, including personal protective equipment and medical surveillance for personnel;
  - (c) procedures to respond to incidents or accidents involving biological agents and toxins;

<sup>21</sup> States may wish to consider preparing these regulations in line with the *World Health Organization's Laboratory Biosafety Manual (4th Edition)*, 2020.

- (d) physical protection;
- (e) personnel access controls, security clearance of personnel and protection of sensitive information;
- (f) periodic review of risk assessments to mitigate biosafety and biosecurity risks and identify dual-use research of concern;
- (g) periodic training of personnel on biosafety and biosecurity.

### **Box 18 – Information security**

While states may decide to include in legislation a requirement for facilities working with dangerous biological agents and toxins to establish information security measures, the specific measures to identify, protect, and control access to sensitive information related to dangerous biological agents and toxins may be better placed in regulations.<sup>22</sup>

For example, states may wish to include the following measures in regulations:

- Policies and procedures to manage the identification, handling, storage, transmission, access control, and destruction of sensitive information;
- A review and approval process to prevent the unauthorised or unintended disclosure of sensitive information;
- Controls to prevent malicious code (such as, but not limited to, computer viruses and spyware) from compromising relevant information systems;
- Backup security measures in the event that information systems (such as, but not limited to, access control systems and surveillance devices) are rendered inoperable.

## **Section/Article 21: Record-keeping**

### ***Record-keeping by the licensee***

- (1) Every licensee under Section/Article 15 shall –
  - (a) Keep and maintain data, information and documents related to activities involving listed biological agents and toxins, equipment and technology, as specified by the regulations issued under this [Act/Law];
  - (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.

### ***Record-keeping by the [responsible authority]***

- (2) The [responsible authority] shall maintain an accurate and current record of all licensees under this Section/Article, including the names and locations of the licensees, and information on the listed biological agents or toxins each licensee is licensed to develop, acquire, manufacture, possess, store, transport, domestically or internationally transfer or use.

## **Section/Article 22: Transport of listed biological agents and toxins**

- (1) Regulations issued by the [responsible authority] under this [Act/Law] shall establish requirements for the safe and secure transport of listed biological agents and toxins.

22 For further reference, see the *International Organization for Standardization's ISO 35001:2019(E) on Biorisk management for laboratories and other related organisations*, section 7.5.4.

- (2) Regulations issued under subsection (1) shall take into account the UN Model Regulations on the Transport of Dangerous Goods, as reflected in the [relevant national legislation on transport], including measures to track listed biological agents and toxins and to confirm receipt of the transfer, such that strict accountability for listed biological agents and toxins is maintained at all times.

#### **Box 19 – Transport legislation**

Measures detailing the safety and security requirements for transporting biological agents and toxins may already exist in different national legislation, for example, in laws controlling transport of dangerous goods.

Where measures do exist in a separate law, states may still consider referring to that law in their BWC implementing legislation and require explicitly that listed biological agents and toxins are only transported in accordance with the relevant legislation.

## CHAPTER 6

# BIOLOGICAL EMERGENCIES AND INCIDENTS

### Box 20 – Defining biological emergencies and other biological incidents

This Model Law uses the generic phrase ‘biological emergencies and other biological incidents’ to overall address in this chapter preparedness and response to sudden or unexpected situations involving biological agents and toxins. As used here, biological incidents may be understood as any ‘occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm’<sup>23</sup>, while (national) biological emergencies may be understood as major biological incidents such as disease outbreaks, public health emergencies or serious security incidents involving biological agents and toxins. How these situations will be referred to and eventually differentiated in the legislation will depend on the relevant national laws in place in each state.

### Section/Article 23: Obligations of licensees

- (1) Every licensee, including transporters/carriers, under Section 15, shall immediately notify the [responsible authority] and the [appropriate law enforcement agency(ies)] of the theft, loss or release of listed biological agents or toxins.
- (2) Every licensee shall establish procedures for the notification of theft, loss or release of listed biological agents or toxins and a facility emergency preparedness and response plan.

### Section/Article 24: National preparedness and response to biological emergencies and incidents

- (1) The [responsible authorities] shall establish procedures to coordinate preparedness, detection, response and investigation of biological emergencies and other biological incidents by [relevant health, emergency services and law enforcement agencies].
- (2) The procedures referred to in subsection (1) shall include the development of a national preparedness and response plan for biological emergencies and other biological incidents, based on the national assessment of biological threats and risks.

### Box 21 – Emergency management legislation

Measures detailing emergency response to, as well as surveillance and detection of, biological incidents may already exist in a state’s emergency/disaster management, disease control, quarantine or other legislation. A state should therefore assess its existing laws in order to check that, if such a law exists, biological incidents and emergencies are covered by its provisions and that the law facilitates cooperation between public, animal and plant health agencies and law enforcement agencies. States should also consider aligning their national legislation on disaster management with the World Health Organization’s International Health Regulations. National policies should consider allocating the resources required for establishing and maintaining capabilities for effective surveillance, detection and response to biological emergencies and other biological incidents.

### Section/Article 25: Transmission of information by the [responsible authority]

In the instance of a biological emergency or other biological incident impacting human, animal or plant health, the [responsible authority] shall be authorised to transmit relevant data and information obtained under this [Act/Law] to other states and international organisations.

23 See *World Health Organization Laboratory Biosafety Manual, 4th edition, page xiii.*

## CHAPTER 7

### FINAL PROVISIONS

#### Section/Article 26: Regulations

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The [Minister or other competent authority] may make such regulations as are necessary to carry out the purposes and provisions of this [Act/Law].

#### Box 22 – Final provisions

Final provisions may vary according to the legal traditions of individual states. These may include provisions specifying commencement and entry into force of the [Act/Law], legislative amendments and transitional measures.

The enactment of an Act/Law implementing the Biological Weapons Convention may require repealing or amending national laws in various fields, such as penal, trade, health or environmental legislation. Depending on the national legal system, such repeals or amendments may be put in place through the new law or referred to separate legislative action within a specified timeline.

Transitional measures may include provisions with timelines or procedures to enable persons conducting regulated activities to comply with any new requirements established under the Act/Law, for example, applying for a licence. These may also include timelines for the development of the necessary regulations by the responsible authority.

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