# **crimes (biological weapons) regulations 2019**

# **EXPLANATORY STATEMENT**

Issued by authority of the Attorney-General

under subsection 13(1) of *Crimes (Biological Weapons) Act 1976*

**INTRODUCTION**

The *Crimes (Biological Weapons) Act 1976* (the Act) gives effect to the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction,* which was signed on behalf of Australia on 10 April 1972. The Act provides a legislative framework prohibiting the development, production, stockpiling or other acquisition of microbial or other biological agents, or toxins, that have no justification for prophylactic, protective or other peaceful purposes, or of biological weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, and for dealing with their seizure.

Paragraph 13(1)(a) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, for and in relation to procedures to be followed in the storage and disposal of substances and articles in respect of which an offence under the Act has been, or is alleged to have been, committed. Under subsection 13(2), the Minister for Home Affairs, as the Minister administering the *Australian Federal Police Act 1979,* is the rule-maker for these regulations.

Paragraph 13(1)(b) provides that the Governor-General may make regulations, not inconsistent with the Act, for and in relation to providing an opportunity for a person charged with an offence under the Act in respect of a microbial or other biological agent, or toxin, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, to have a sample of that substance analysed on the person’s behalf. The Attorney-General is the rule-maker for these regulations.

The *Crimes (Biological Weapons) Regulations 1980* (the current Regulations) are made under subsection 13(1) of the Act. The current Regulations set out the procedures and requirements to be followed in relation to the notification, storage, labelling and disposal of microbial or other biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes, or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes in armed conflict.

The current Regulations also enable a person charged with an offence under the Act in respect of a microbial or other biological agent or toxin that has no justification for prophylactic, protective or other peaceful purposes, to seek an independent analysis of a sample of a substance.

Under section 50 of the *Legislative Instruments Act 2003*, the current Regulations are due to sunset on 1 April 2019. They were originally due to sunset on 1 April 2018 but this date was deferred under paragraph 51(1)(c) of the *Legislative Instruments Act 2003.[[1]](#footnote-1)*

**Purpose and operation of the Instrument**

The purpose of the *Crimes (Biological Weapons) Regulations 2019* (the new Regulations) is to continue the arrangements presently set out in the current Regulations after the current Regulations sunset. Accordingly, the new Regulations are substantively the same as the current Regulations. Minor changes have been made including to ensure consistency with modern drafting conventions and to update outdated references. Once they take effect, the new Regulations will repeal and replace the current Regulations.

**Consultation**

Pursuant to section 17 of the *Legislative Instruments Act 2003* the rule-makers are satisfied that appropriate and reasonably practical consultation has occurred, particularly given that the new Regulations do not substantially alter existing arrangements.

Consultation was undertaken with key stakeholders. Government agencies with a role in relation to the legislative scheme, namely the Department of Health, Department of Home Affairs and the Australian Federal Police, were consulted in the development of the new Regulations. The Commonwealth Director of Public Prosecutions was also consulted in relation to prosecutions under the *Crimes (Biological Weapons) Act 1976.*

**Regulation Impact Statement**

The regulatory impact of the new Regulations was assessed through completion of a Regulation Impact Statement (RIS) Preliminary Assessment. On the basis of this assessment, the Office of Best Practice Regulation advised that a RIS was not required (OBPR ID: 23029).

**OTHER DETAILS**

The new Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003.*

Details of the new Regulations are at **Attachment A**. A Statement of Compatibility under subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011* is at **Attachment B**.

**Attachment A**

**NOTES ON SECTIONS**

**Part 1 – Preliminary**

**Section 1 – Name**

This section provides that the title of the new Regulations is the *Crimes (Biological Weapons) Regulations 2019*.

**Section 2 – Commencement**

This section provides that the new Regulations will commence on the day after the Regulations are registered.

**Section 3 – Authority**

This section provides that the new Regulations are made under the *Crimes (Biological Weapons) Act 1976* (the Act)*.*

**Section 4 – Purpose of this instrument**

This section set out the purposes of the new Regulations. These are to set out:

* the procedures to be followed in the storage and disposal of microbial or other biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, or of weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, and
* the manner in which a person accused of an offence under the Act can seek to have a sample of a microbial or other biological agent, or toxin, analysed on their behalf.

**Section 5 – Schedules**

This section provides that each instrument that is specified in a Schedule to the new Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the new Regulations has effect according to its terms.

**Section 6 – Definitions**

This section defines the relevant terms for the purposes of the new Regulations. It updates and modernises some of the definitions in the current Regulations*.*

The term ***prohibited item*** is defined to capture all substances and articles whose development, production, stockpiling or other kind of acquisition the Act prohibits.

**Part 2 – Prohibited items**

**Section 7 – Acquisition, storage and labelling of prohibited items**

This section sets out the requirements with which persons who acquire a prohibited item on behalf of the Commonwealth must comply.

Subsection 7(1) requires a person who acquires a prohibited item on behalf of the Commonwealth to notify the Commonwealth Chief Medical Officer as soon as practicable, in writing, that the person has acquired the prohibited item. This is so that the Commonwealth Chief Medical Officer is aware that the Commonwealth has obtained a potentially dangerous or harmful substance or article and can ensure appropriate arrangements are made to store them.

Once notified, subsection 7(2) requires the Commonwealth Chief Medical Officer to give written directions in relation to the storage of the prohibited item as they consider appropriate in the circumstances. The directions will provide guidance about how the substance or article is to be securely and appropriately stored.

These directions would not be a legislative instrument within the meaning of subsection 8(4) of the *Legislation Act 2003.* This is because directions given under subsection 7(2) would likely be exempt from legislative instrument status under item 5 of the table in section 6 of the *Legislation (Exemptions and Other Matters) Regulation 2015*, which provides that an instrument the effect of which is to approve a manner or method of doing an act is not a legislative instrument. A direction given under subsection 7(2) would merely be declaratory of the law and not legislative in character under subsection 8(4) of the *Legislation Act 2003,* and would not be intended to be a substantive exemption from the *Legislation Act 2003.*

Subsection 7(3) sets out examples of the kinds of matters which the Commonwealth Chief Medical Officer’s directions may cover. These include the place at which the prohibited item is to be stored, the temperature and relative humidity at which the prohibited item is to be stored, and the type of container in which the prohibited item is to be stored. These examples are not intended to in any way limit the directions that the Commonwealth Chief Medical Officer may make about the storage of the prohibited item under subsection 7(2).

Subsection 7(4) requires that a person who is responsible for the storage of a prohibited item must comply with any written direction given under subsection (2) in relation to the item.

Subsection 7(5) specifies the labelling requirements with which a person who is responsible for the storage of a prohibited item must comply. These requirements are intended to ensure that the substance or article, the chain of custody, and any dealings with the prohibited item, are clearly identified and recorded.

**Section 8 – Disposal of prohibited items**

Subsection 8(1) prohibits a person from disposing of a prohibited item unless they do it in accordance with any written directions of the Commonwealth Chief Medical Officer under subsection 8(2). This is important to ensure that a potentially dangerous and harmful substance or article is properly disposed of, and only after it has been determined there is no longer a need to store it.

Subsection 8(2) allows the Commonwealth Chief Medical Officer to give such directions, in writing, in relation to the disposal of a prohibited item as the Commonwealth Chief Medical Officer considers necessary. In giving such directions, the Commonwealth Chief Medical Officer is to have regard to the requirements of public health and safety, and the effect of the disposal of the prohibited item on plants and animals. This is crucial given the potential for a prohibited item, such as a biological toxin, to cause significant damage to human or animal health, and the environment.

These directions would not be a legislative instrument within the meaning of subsection 8(4) of the *Legislation Act 2003.* This is because directions given under subsection 8(2) would likely be exempt from legislative instrument status under item 5 of the table in section 6 of the *Legislation (Exemptions and Other Matters) Regulation 2015*, which provides that an instrument the effect of which is to approve a manner or method of doing an act is not a legislative instrument. A direction given under subsection 8(2) would merely be declaratory of the law and not legislative in character under subsection 8(4) of the *Legislation Act 2003,* and would not be intended to be a substantive exemption from the *Legislation Act 2003.*

**Section 9 – Analysis of certain substances**

This section sets out the manner in which a person accused of an offence under the Act (the ***offender***) in respect of a microbial or other biological agent, or toxin, can seek to have a sample of the agent or toxin analysed on their behalf. This ensures that an offender can request an independent assessment of the agent or toxin and, therefore, can properly prepare their defence and challenge the Crown’s evidence. As the Act makes it an offence to acquire or retain such a substance, this section provides a mechanism for an offender to lawfully provide a sample of the substance to an independent expert and have them test it. This will be at the offender’s own cost. At the same time, in recognition of the extreme danger to the community that these prohibited items pose, this section sets out important controls on access to them.

Subsection 9(1) enables the offender to nominate another person (the ***nominee***) to analyse a sample of the substance on the offender’s behalf. The offender must then request in writing that the Commonwealth Chief Medical Officer permit the nominee to analyse the sample.

Subsection 9(2) requires the Commonwealth Chief Medical Officer to be satisfied that the nominee is competent to analyse the sample because of the nominee’s training and experience. If so satisfied, the Officer must permit, in writing, the nominee to analyse the sample. It is important that the Officer has the power to refuse permission if the nominee is not appropriately qualified because an approved nominee will have access to a sample of a microbial or other biological agent, or toxin, which could cause damage or harm to human or animal health or the environment.

A permission given under subsection 9(2) would not be a legislative instrument within the meaning of subsection 8(4) of the *Legislation Act 2003.* This is because a permission would likely be exempt from legislative instrument status under item 4 of the table in section 6 of the *Legislation (Exemptions and Other Matters) Regulation 2015*, which provides that an instrument that has the effect of authorising or approving a particular person to take a particular action or act in a particular way is not a legislative instrument. A permission given under subsection 9(2) would merely be declaratory of the law and not legislative in character under subsection 8(4) of the *Legislation Act 2003,* and would not be intended to be a substantive exemption from the *Legislation Act 2003.*

If the Commonwealth Chief Medical Officer permits the nominee to analyse the sample, subsection 9(3) sets out the following conditions with which the Officer must comply:

* make a sample of the substance available for analysis by the nominee
* specify, in writing, a time and place for the nominee to analyse the sample, and
* maintain control of the sample while the sample is analysed.

These strict controls are necessary because the microbial or other biological agent, or toxin, could cause significant damage to human or animal health, or the environment, and the only substances caught by the Act are those without a prophylactic, protective or other peaceful purpose. Accordingly, it is particularly important that the Officer maintains control of the sample while a nominee analyses it.

Subsection 9(4) imposes certain restrictions on the time and place that a nominee may analyse the sample. The Commonwealth Chief Medical Officer must specify a time and place that is reasonable in the circumstances, having regard to the nature of the sample to be analysed, and the requirements of public health and safety.

**Section 10 – Delegation**

Subsection 10(1) allows the Commonwealth Chief Medical Officer to delegate, in writing, all or any of the Officer’s functions or powers under the new Regulations to senior officers in the Health Department, namely an SES employee or acting SES employee. The expressions ‘SES employee’ and ‘acting SES employee’ are defined in section 2B of the *Acts Interpretation Act 1901.* The potential delegates are appropriately confined to senior employees of the Department of Health which is responsible for the health-related matters to which the Act and new Regulations relate.

Subsection 10(2) requires a delegate to comply with any written directions of the Commonwealth Chief Medical Officer in performing a delegated function or exercising a delegated power.

**Schedule 1 – Repeals**

**Item 1**

Item 1 repeals the *Crimes (Biological Weapons) Regulations 1980.*

**Attachment B**

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***Crimes (Biological Weapons) Regulations 2019***

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the *Crimes (Biological Weapons) Regulations 2019***

The *Crimes (Biological Weapons) Regulations 2019* (the new Regulations) remakes the *Crimes (Biological Weapons) Regulations 1980* (the current Regulations).

The current Regulations are made under the *Crimes (Biological Weapons) Act 1976* (the Act), which provides a legislative framework prohibiting the development, production, stockpiling or other acquisition of microbial or other biological agents, or toxins, that have no justification for prophylactic, protective or other peaceful purposes, or of biological weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict, and for dealing with their seizure.

Paragraph 13(1)(a) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, for and in relation to procedures to be followed in the storage and disposal of substances and articles in respect of which an offence under the Act has been, or is alleged to have been, committed.

Paragraph 13(1)(b) provides that the Governor-General may make regulations, not inconsistent with the Act, for and in relation to providing an opportunity for a person charged with an offence under the Act in respect of a microbial or other biological agent, or toxin, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes, to have a sample of that substance analysed on their behalf.

The current Regulations set out the procedures and requirements to be followed in relation to the notification, storage, labelling and disposal of microbial or other biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes, or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes in armed conflict.

The current Regulations also enable a person charged with an offence under the Act in respect of a microbial or other biological agent or toxin that has no justification for prophylactic, protective or other peaceful purposes, to seek an independent analysis of a sample of the substance.

The purpose of the new Regulations is to continue the arrangements presently set out in the current Regulations after the current Regulations sunset. Accordingly, the new Regulations are substantively the same as the current Regulations. Minor changes have been made including to ensure consistency with modern drafting conventions and to update outdated references. Once they take effect, the new Regulations will repeal and replace the current Regulations.

**Human rights implications**

The new Regulations engage the following rights:

* right to a fair trial and fair hearing, and
* right to health.

***Right to fair trial and fair hearing***

Article 14 of the International Covenant on Civil and Political Rights sets out the right to a fair criminal trial and establishes a number of guarantees that must be observed in criminal proceedings. Paragraph (1) stipulates that all persons shall be equal before the courts and tribunals and that in determining a criminal charge, a person is entitled to a fair and public hearing. Paragraphs (3), (5), (6) and (7) establish a number of guarantees that must be observed in criminal proceedings. These include the ability of a person to prepare and defend themselves in criminal proceedings.

The new Regulations engage this right insofar as they regulate the manner in which a person accused of an offence under the Act involving a microbial or other biological agent or toxin can have a sample of the substance independently analysed on their behalf.

Section 9 allows a person charged with an offence under the Act in respect of a biological agent or toxin to request a nominee to analyse a sample of the substance on their behalf. However, it also includes controls regarding the analysis of the substance. The Commonwealth Chief Medical Officer must permit the nominee to analyse the sample but only if satisfied that the nominee is competent to do so because of the nominee’s training and experience. The Commonwealth Chief Medical Officer must maintain control of the sample while it is analysed. While these are limitations on the right to fair trial and fair hearing, they are aimed at achieving the legitimate objective of protecting public health, are rationally connected to this purpose, and are reasonable, necessary, and proportionate.

The controls and processes in section 9 only arise in respect of an offence, or alleged offence, involving a microbial or other biological agent, or toxin, of a type or in a quantity that has no justification for prophylactic, protective or other peaceful purposes. Such agents or toxins may have wide-ranging, uncertain and detrimental health and other impacts on the community. It is reasonable, necessary and proportionate, to require such substances to be handled and tested only by people with appropriate qualifications and experience in dealing with such dangerous and harmful substances given the potential for significant damage or harm to human or animal health, or the environment.

The importance of protecting public health is expressly contemplated in subsection 9(4) which requires the Commonwealth Chief Medical Officer to have regard to the nature of the sample to be analysed and the requirements of public health and safety in specifying a reasonable time and place for a nominee to analyse the sample, and in the strict requirements imposed on the storage, labelling and disposal of these substances in other sections of the Regulations.

Therefore, the new Regulations enable the independent analysis of substances but with appropriate, proportionate and clear processes in place to ensure protection of public health.

***Right to health***

The right to health is contained in article 12(1) of the International Covenant on Economic Social and Cultural Rights. The right to health is the right to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights has stated that health is a fundamental human right indispensable for the exercise of other human rights. The right to health encompasses the right to be free from interference with one’s health.

Microbial or other biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes may have wide-ranging, uncertain and detrimental health and other impacts on the community.

The new Regulations promote and protect the right to health of the Australian community insofar as they provide for the proper and safe handling, storage and disposal of microbial or other biological agents or toxins that have no legitimate justification. The new Regulations enable the Commonwealth Chief Medical Officer, who has the necessary knowledge and experience to manage any risks associated with such substances, to issue appropriate directions and permissions. The new Regulations expressly provide that in issuing any directions to dispose of a prohibited item, the Commonwealth Chief Medical Officer must have regard to the requirements of public health and safety, and the effect of the disposal on plants and animals.

As discussed above, the new Regulations enable a person charged with an offence under the Act in respect of an agent or toxin to nominate a suitably qualified person to analyse a sample of that substance. The Regulations expressly provide that in specifying a time and place at which the nominated person is to analyse the sample, the Commonwealth Chief Medical Officer must have regard to the requirements of public health and safety.

Accordingly, the Regulations engage and expressly promote the right to health of persons who are tasked with managing and handling prohibited substances, as well as the broader Australian community.

**Conclusion**

The new Regulations are compatible with human rights because they promote the protection of the right to health, and to the extent that they may limit the right to a fair trial and fair hearing rights, those limitations are reasonable, necessary and proportionate.

1. *Legislation (Deferral of Sunsetting – Crimes (Biological Weapons) Regulations) Certificate 2018* [↑](#footnote-ref-1)