

EXPLANATORY STATEMENT

Issued by Authority of the Director of Biosecurity and the Director of Human Biosecurity

Biosecurity Act 2015

*Biosecurity (Conditionally Non-prohibited Goods) Amendment (Test Kits) Determination
2021*

Legislative Authority

The *Biosecurity Act 2015* (the Act) provides the regulatory framework for the management of diseases and pests that may cause harm to human, animal or plant health or the environment.

The Act also gives effect to Australia's relevant international rights and obligations, including Australia's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement provides for Australia's obligations with respect to the Appropriate Level of Protection (ALOP), which, for Australia, is a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not zero.

Subsection 174(1) of the Act provides that the Director of Biosecurity and Director of Human Biosecurity may jointly determine that specified classes of goods must not be brought or imported into Australian territory unless specified conditions (including conditions for administrative purposes) are complied with.

Under subsection 174(3) of the Act, the Director of Biosecurity and the Director of Human Biosecurity must apply the ALOP for Australia in conducting a risk assessment for the purpose of deciding whether to make a determination under subsection 174(1).

Under paragraph 541(4)(a) of the Act, in performing functions or exercising powers under the Act, including making a determination under section 174, the Director of Biosecurity must have regard to the objects of the Act, which relevantly include providing for managing biosecurity risks and giving effect to Australia's international rights and obligations.

Purpose

The purpose of the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (Test Kits) Determination 2021* (Amendment Determination) is to amend the *Biosecurity (Conditionally Non-prohibited) Goods Determination 2021* (Goods Determination) to facilitate the importation of test kits, including particular COVID-19 test kits, containing animal material, human material or material derived from a disease agent.

To achieve this, the Amendment Determination amends the Goods Determination to provide that test kits must not be brought or imported into Australian territory unless they are covered by an import permit or the alternative conditions specified for such test kits are complied with. The provision of alternative conditions for test kits means that an import permit is not required for the import of test kits provided that the alternative conditions are met.

Background

The Department of Agriculture, Water and the Environment (the department) and the Department of Health co-administer the Act, which establishes the framework for biosecurity risk management. The detail and specific information requirements for certain activities under the Act are provided for in the *Biosecurity Regulation 2016* and other delegated legislation, including the Goods Determination.

Goods entering Australia carry a risk that they may introduce pests and diseases that could have a negative impact on the environment or human, plant or animal health. To regulate the bringing or importing of goods into Australian territory, the department identifies priority pests and diseases of concern and identifies the measures to be put in place to manage the biosecurity risks associated with specified classes of goods. In determining the appropriateness of the measures, the department evaluates the likelihood of entry, establishment or spread of a pest or disease within Australian territory, as well as the associated potential harm and economic consequences, in accordance with the ALOP for Australia.

Impact and Effect

The Amendment Determination ensures that an import permit will not be required for test kits (including COVID-19 test kits) containing animal material, human material or material derived from a disease agent provided that certain alternative conditions are met. These alternative conditions for test kits manage the biosecurity risks to the ALOP for Australia.

This results in a decrease in administrative burden, for both the department and the importers, without compromising the management of biosecurity risks to facilitate trade, which aligns with the Government's trade agenda.

Consultation

The department has prepared the Amendment Determination in consultation with the Department of Health and the Therapeutic Goods Administration.

The department also worked closely with industry representatives and importers, including Pathology Technology Australia, the Public Laboratory Health Network and the department's Biologicals Consultative Group. The Amendment Determination reflects the feedback and communication with regulated entities, stakeholders, industry and with various areas of the department.

The Office of Best Practice Regulation has approved a standing exemption from the Regulatory Impact Statement Preliminary Assessment (RIS) process for minor or technical amendments, or amendments that are in line with the current biosecurity policy setting and do not have more than a minor regulatory impact on industry, to the Goods Determination (ID 23368). Accordingly, a RIS has not been conducted for the Amendment Determination.

Details/Operation

Details of the Amendment Determination are set out in [Attachment A](#).

This Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003* (the Legislation Act). Subsection 174(5) of the Act provides that the Amendment Determination is not subject to disallowance. It is appropriate for the Amendment Determination to be exempt from disallowance because the decision to make a determination under subsection 174(1) of the Act relies solely on technical and scientifically-based evidence to specify conditions required to be complied with to meet the ALOP for Australia in relation to the bringing in or importation of conditionally non-prohibited goods, such as test kits. The specified conditions assist with reducing the level of biosecurity risks of specific pests and diseases of biosecurity concern associated with the importation of test kits containing animal material, human material, or material derived from a disease agent. The conditions are based on the latest scientific and technical information available, including to ensure the complete or partial inactivation of disease agents and use of purification processes that target a specific biomolecule while removing extraneous material and contaminating disease agents. This exemption from disallowance is in accordance with paragraph 44(2)(a) of the Legislation Act. As the Amendment Determination is exempt from disallowance, this also means that a Statement of Compatibility with Human Rights is not required in accordance with paragraph 15J(2)(f) of the Legislation Act and subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

The Amendment Determination commences the day after it is registered as an instrument.

Details of the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (Test Kits) Determination 2021*

Section 1—Name

This section provides that the name of the legislative instrument is the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (Test Kits) Determination 2021* (the Amendment Determination).

Section 2—Commencement

This section provides that the Amendment Determination commences the day after the instrument is registered.

Section 3—Authority

This section provides that the Amendment Determination is made under subsection 174(1) of the *Biosecurity Act 2015*.

Section 4—Schedules

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

Schedule 1—Amendments

Item 1 At the end of subsection 11(2)

Item 1 inserts new paragraph 11(2)(f) at the end of subsection 11(2) of the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* (the Goods Determination) to ensure that a test kit containing animal material, human material or material derived from a disease agent is not a class of goods to which Division 1 of Part 2 of the Goods Determination applies.

Division 1 of Part 2 of the Goods Determination sets out the conditions applying to certain classes of goods relating to animals, plants, biological material and infectious agents. Section 11 of the Goods Determination lists the classes of goods to which this Division applies, including goods containing, or made of, animal material. Subsection 11(2) lists exceptions to those classes of goods.

This amendment provides that test kits referred to in new section 54A of the Goods Determination, as inserted by item 2 of this Schedule, is not a class of goods to which Division 1 of Part 2 of the Goods Determination applies. The purpose of this amendment is to ensure that only the new conditions set out in Division 2 of Part 2 of the Goods Determination apply to these test kits.

Item 2 At the end of Division 2 of Part 2

Item 2 inserts new section 54A at the end of Division 2 of Part 2 of the Goods Determination.

New section 54A of the Goods Determination provides that test kits that contain animal material, human material or material derived from a disease agent, as described by new subsection 54A(1), must not be brought or imported into Australian territory unless they are covered by an import permit or the alternative conditions listed in subsection 54A(3) are met.

New subsection 54A(2) provides that these test kits must not be brought or imported into Australian territory unless either the goods are covered by an import permit, or all of the following alternative conditions apply, as set out in subsection 54A(3):

- the goods are a medical device that is included in the Register within the meaning of the *Therapeutic Goods Act 1989* (the TG Act) (paragraph 54A(3)(a));
- the goods have not been included in the Register for the sole purpose of being brought or imported into Australia for export only (paragraph 54A(3)(b));
- the goods are an immunochromatographic device (paragraph 54A(3)(c));
- the goods are finished goods that are packed in their final packaging (paragraph 54A(3)(d));
- the goods have been manufactured using a production process that implements validated methods of elimination or inactivation of disease agents present in the goods (paragraph 54A(3)(e));
- the goods are not intended for veterinary therapeutic use (paragraph 54A(3)(f));
- no animal or plant is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the goods (paragraph 54A(3)(g));
- the animal material, human material or material derived from a disease agent (the relevant material) that is contained in the goods is adhered to an inert membrane substrate or in a solution, or both (paragraph 54A(3)(h));
- if the relevant material is in a solution, the solution is an integral component of the test kit, and the amount of the relevant material contained in each solution that is a component of the test kit does not exceed 2mL (paragraph 54A(3)(i));
- the goods are accompanied by written evidence from, or a written declaration by, the manufacturer of the goods stating (paragraph 54A(3)(j)):
 - whether the relevant material that is contained in the goods is adhered to an inert membrane substrate, in a solution or both; and
 - that the goods have been manufactured using a production process that implements validated methods of elimination or inactivation of disease agents present in the goods; and
 - if any of the relevant material contained in the test kit is in one or more solutions that are a component of the test kit - that the material in each solution does not exceed 2 mL.

Paragraphs 54A(3)(a) and (b) - Medical device included in the Register that are not for export

The Australian Register of Therapeutic Goods is maintained under section 9A of the TG Act. New paragraphs 54A(3)(a) and (b) provide that where the goods are a medical device that is included in the Register for the sole purpose of being brought or imported into Australia for export only, they will not meet the alternative conditions under new subsection 54A(3) of the

Goods Determination. Where goods have been included on the Register as a medical device both for sale in Australia and for export, the alternative condition set out in new paragraph 54A(3)(b) can still be met. The Register is available to the public on the Therapeutic Goods Administration's website. This new provision reflects the intention of the amendments to facilitate the import of test kits for supply in Australia.

Paragraph 54A(3)(c) – Goods are an immunochromatographic device

New paragraph 54A(3)(c) ensures that to meet the alternative conditions, the goods must be an immunochromatographic device. The intention is that the test kits cannot be brought or imported into Australian territory in accordance with the alternative conditions in new subsection 54A(3) of the Goods Determination unless it is based on a certain type of diagnostic mechanism.

Paragraph 54A(3)(d) – Goods are finished goods packed in their final packaging

New paragraph 54A(3)(d) ensures that to meet the alternative conditions, the goods must be finished goods, that is, that they have completed the manufacturing process, and they are packed in their final packaging. The intention is that the test kits cannot be brought or imported into Australian territory in accordance with the alternative conditions in new subsection 54A(3) of the Goods Determination if the goods still require further processing before they are sold or supplied for use in Australia.

Paragraph 54A(3)(e) – Goods have been manufactured using a production process that implements validated methods of elimination or inactivation of disease agents present in the goods

New paragraph 54A(3)(e) provides that the goods must have been manufactured using a production process that implements validated methods of elimination or inactivation of disease agents present in the goods. The appropriate validated method to meet the alternative condition will depend on the in vitro diagnostic technology used in, and the particular characteristics of, the particular goods.

The intention is that the test kits cannot be brought or imported into Australian territory in accordance with the alternative conditions in new subsection 54A(3) of the Goods Determination if the goods contain active disease agents.

Paragraphs 54A(3)(f) and (g) – Goods must not be intended for veterinary therapeutic use, and no animal or plant can be exposed to the goods

New paragraphs 54A(3)(f) and (g) provide that to meet the alternative conditions, the goods must not be intended for veterinary therapeutic use, and that no animal or plant is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the goods after the finished goods have been brought or imported into Australian territory. The term ***veterinary therapeutic use*** is defined in section 6 of the Goods Determination to mean use in or in connection with preventing, diagnosing, curing or alleviating a disease or condition in animals or the infestation of animals by a pest; curing or alleviating an injury suffered by animals; or influencing, inhibiting or modifying a physiological process associated with a disease or condition in animals.

The purpose of these conditions is that the goods, or derivatives of the goods, must not come into contact with any animal for any use after they have been brought or imported into Australian territory, whether that is a veterinary therapeutic use or, more broadly, any other use that involves coming into contact with one or more animals. Further, the goods, or derivatives of the goods, must not come into contact with any plant after the finished goods have been brought or imported into Australian territory.

Paragraphs 54A(3)(h) and (i) – Material must be adhered to an inert membrane substrate or in a solution of 2mL or less

New paragraphs 54A(3)(h) and (i) provide that to meet the alternative conditions, the animal material, human material or material derived from a disease agent (the relevant material) that is contained in the goods must be either:

- adhered to an inert membrane substrate (in any quantity); or
- in a solution; or
- both.

If the relevant material is in a solution, the solution must be an integral component of the test kit and the amount of the relevant material contained in each solution must not exceed 2mL.

The intention of this provision is to cover the situation where a test kit includes a solution, such as a buffer solution, that is used as part of the kit and not sold separately. In this instance, the solution containing the relevant material must be an integral component of the test kit and the relevant material in the solution must not exceed 2mL in volume. This is in addition to any relevant material adhered to the inert membrane substrate. For example, it would be acceptable to have:

- 3mL of relevant material adhered to the substrate as well as 1.5mL of relevant material in a solution that is separate from the substrate;
- a 7mL solution containing substances other than the relevant material, provided that the part of the solution that consists of the relevant material does not exceed 2mL;
- more than one solution that is an integral component of the test kit, each of which contains relevant material not exceeding 2mL.

Paragraphs 54A(3)(j) – Written evidence or declaration is required

New paragraph 54A(3)(j) provides that the goods must be accompanied by written evidence from, or a written declaration by, the manufacturer of the goods stating certain matters.

New subparagraph 54A(3)(j)(i) provides that the goods must be accompanied by written evidence or declaration stating whether the relevant material that is contained in the goods is adhered to an inert membrane substrate, in a solution or both. An example of written evidence would be the paper instructions leaflet found inside the product's packaging.

New subparagraph 54A(3)(j)(ii) provides that the goods must be accompanied by written evidence or a declaration stating that the goods have been manufactured using a production process that implements validated methods of elimination or inactivation of disease agents present in the goods.

New subparagraph 54A(3)(j)(iii) provides that if the relevant material is in one or more solutions that are an integral component of the test kit, the goods must be accompanied by written evidence or a declaration stating that the relevant material in each solution does not exceed 2mL.

The alternative conditions for test kits in new subsection 54A(3) of the Goods Determination are appropriate to manage the biosecurity risks associated with the importation of test kits that contain animal material, human material or material derived from a disease agent and are effective in meeting the ALOP for Australia.

If the alternative conditions for test kits are not met, new subsection 54A(2) of the Goods Determination provides that the goods must not be brought or imported into Australian territory unless the goods are covered by an import permit.