



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

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We, Andrew Edgar Francis Metcalfe AO, Director of Biosecurity, and Professor Paul Kelly, Director of Human Biosecurity, make the following determination.

Dated 30 November 2021

Andrew Edgar Francis Metcalfe AO  
Director of Biosecurity

Professor Paul Kelly  
Director of Human Biosecurity

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## 1 Name

This instrument is the *Biosecurity (Conditionally Non-prohibited Goods) Amendment (Test Kits) Determination 2021*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	4 December 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 174(1) of the *Biosecurity Act 2015*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

## Schedule 1—Amendments

### *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021*

#### **1 At the end of subsection 11(2)**

Add:

; (f) test kits referred to in section 54A.

#### **2 At the end of Division 2 of Part 2**

Add:

#### **54A Test kits**

*Classes of goods to which this section applies*

- (1) The class of goods to which this section applies is test kits that contain animal material, human material or material derived from a disease agent.

*Conditions*

- (2) Goods included in the class of goods to which this section applies must not be brought or imported into Australian territory unless:
  - (a) the goods are covered by an import permit; or
  - (b) the alternative conditions specified for the goods in subsection (3) are complied with.
- (3) For paragraph (2)(b), the alternative conditions for bringing or importing the goods into Australian territory are:
  - (a) the goods are a medical device that is included in the Register (within the meaning of the *Therapeutic Goods Act 1989*); and
  - (b) the goods have not been included in the Register for the sole purpose of being brought or imported into Australia for export only; and
  - (c) the goods are an immunochromatographic device; and
  - (d) the goods are finished goods that are packed in their final packaging; and
  - (e) 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
  - (f) the goods are not intended for veterinary therapeutic use; and
  - (g) no animal or plant is, or will be, exposed (whether directly or indirectly) to the goods or any derivatives of the goods; and
  - (h) the animal material, human material or material derived from a disease agent that is contained in the goods is:
    - (i) adhered to an inert membrane substrate; or
    - (ii) in a solution; or
    - (iii) both adhered to an inert membrane substrate and in a solution; and
  - (i) if the animal material, human material or material derived from a disease agent is in a solution:
    - (i) the solution is an integral component of the test kit; and

- (ii) the amount of the material contained in each solution that is a component of the test kit does not exceed 2 mL; and
- (j) the goods are accompanied by written evidence from, or a written declaration by, the manufacturer of the goods stating:
  - (i) whether the animal material, human material or material derived from a disease agent that is contained in the goods is adhered to an inert membrane substrate, in a solution or both; and
  - (ii) 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
  - (iii) if any of the animal material, human material or material derived from a disease agent 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.