

EXPLANATORY STATEMENT

Biosecurity Act 2015

Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022

Purpose

The *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022* (“the Determination”) prohibits the practice of price gouging and the exportation of a COVID-19 rapid antigen test kit (RATs), unless an exception to the export restrictions under section 9 of the Determination applies.

Testing for COVID-19 is an essential component of Australia’s management of the COVID-19 pandemic. States and territories, as part of their ongoing response to COVID-19 and the circulating Omicron and Delta variants, have introduced requirements and otherwise recommended people to use RATs in certain circumstances. This is intended to control the spread of COVID-19 within Australia and to limit the pressure on existing state and territory PCR testing. As a result, there is an increasing demand for RATs.

Price gouging is reportedly occurring in Australia, whereby certain persons are purchasing RATs in retail transactions and supplying (or offering to supply) for a price that is much higher than the original purchase price. RATs are a key component of Australia’s public health response to COVID-19, including for the purposes of determining infection with COVID-19 and preventing further onward spread through enabling appropriate isolation and quarantine actions to be taken. Timeliness of the process from testing to notification to the confirmed case, to isolation is critical in Australia’s public health response of controlling the spread of COVID-19. Affordable access to these tests is therefore critical in the management of the pandemic.

The practice of price gouging on the sale of RATs has a disproportionate impact on lower income and more vulnerable individuals. Given the increasing role that RATs play in the management of Australia’s COVID-19 response, affordable access to RATs kits is needed to ensure that patients at increased risk of more severe disease are identified early and that cases are managed. It is therefore necessary to ensure that RAT kits are reasonably and appropriately available to individuals who may be close contacts of COVID-19 cases or who have symptoms consistent with a COVID-19 infection in accordance with the new public health measures.

Price gouging of RAT kits prevents access to critical testing capability for many Australians, including those who are more vulnerable and those from lower socio-economic backgrounds. The opportunity to confirm COVID-19 diagnosis will be compromised, particularly in vulnerable communities with lower vaccination rates and where individuals are most at-risk. This would have a flow on effect on case and contact management in Australia, and the potential to increase the spread of the disease.

The measures in the Determination form part of a suite of measures being implemented by the Government to address the use and availability of RATs in Australia. Notably, the measures included in the Determination will be supplemented by anti-hoarding measures that will be administered and monitored by the retail sector voluntarily to limit the number of RATs that may be supplied to customers. In addition, measures are intended to be put in place to provide certain concession card holders with free access to a number of RATs each month.

The Commonwealth Chief Medical Officer, in his capacity as Director of Human Biosecurity, has advised the Health Minister, and the Health Minister is subsequently satisfied, that these requirements are necessary to prevent or control the spread of COVID-19 in Australian territory or a part of Australian territory.

Specifically, the Director of Human Biosecurity has advised the Health Minister, and the Health Minister is satisfied, that the requirements specified in the Determination are:

- likely to be effective in, or to contribute to, achieving the purpose for which the requirements have been determined;
- appropriate and adapted to that purpose; and
- no more restrictive or intrusive than required in the circumstances, including the manner in which the requirements are to be applied.

Authority

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003* (the Legislation Act).

During a human biosecurity emergency period, the Health Minister may, in accordance with section 477 of the *Biosecurity Act 2015* (“the Biosecurity Act”), determine emergency requirements that are necessary to prevent or control the entry, emergence, establishment or spread of the declaration listed human disease COVID-19 in Australian territory or a part of Australian territory.

Subsection 477(1) of the Biosecurity Act relevantly provides that during a human biosecurity emergency period, the Health Minister may determine any requirement that he or she is satisfied is necessary to:

- prevent or control the entry of the declaration listed human disease into Australian territory or a part of Australian territory, or the emergence, establishment or spread of the declaration listed human disease in Australian territory or a part of Australian territory; or
- prevent or control the spread of the declaration listed human disease to another country; or
- give effect to a recommendation that has been made to the Health Minister by the World Health Organization under Part III of the International Health Regulations in relation to the declaration listed human disease.

Subsection 477(2) of the Biosecurity Act provides that a determination made under subsection 477(1) is a legislative instrument, but section 42 (disallowance) of the

Legislation Act 2003 does not apply to the determination. This is because the risk of such disallowance would inhibit the Commonwealth's ability to act urgently on public health advice to manage a human biosecurity risk that could threaten or harm human health and create uncertainty as to the importance of the public health measure.

Relevantly, subsection 477(5) provides that a determination made under subsection 477(1) applies despite any provision of any Commonwealth, state or territory law. A person commits a criminal offence punishable by a maximum sentence of five years imprisonment, or 300 penalty units (currently \$66,600), or both a person fails to comply with a requirement of a determination that applies to the person (section 479 of the Biosecurity Act refers).

The Australian Government has established protocols for the exercise of emergency powers under the Biosecurity Act to ensure that these powers are only used where necessary to protect the health of Australians, based on expert advice and following appropriate consultation.

Background

On 5 January 2020, the World Health Organization ("WHO") notified Member States under the *International Health Regulations* (2005) regarding an outbreak of pneumonia of unknown cause in Wuhan, China. On 21 January 2020, 'human coronavirus with pandemic potential' became a 'listed human disease' by legislative instrument made by the Director of Human Biosecurity under the Biosecurity Act. On 30 January 2020, the outbreak was declared by the WHO International Regulations Emergency Committee to constitute a Public Health Emergency of International Concern.

On 11 February 2020, the WHO announced that the International Committee on Taxonomy of Viruses named the pathogen virus 'severe acute respiratory syndrome coronavirus (SARS-CoV-2)'. The international name given by the WHO to the disease caused by SARS-CoV-2 is coronavirus disease 2019 (COVID-19). The WHO subsequently declared the outbreak of COVID-19 to be a pandemic on 11 March 2020.

On 18 March 2020, the Governor-General declared in a declaration made under section 475 of the Biosecurity Act that a human biosecurity emergency exists regarding the listed human disease 'human coronavirus with pandemic potential' (*Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) Declaration 2020* refers). The human biosecurity emergency period is currently in force until 17 February 2022 (unless further extended).

COVID-19 has entered Australia and represents a severe and immediate threat to human health in Australia as it has the ability to cause high levels of morbidity and mortality and to disrupt the Australian community socially and economically.

On 27 November 2021, the WHO announced that B.1.1.529 ('Omicron') is a new COVID-19 variant of concern. Public health measures have been put in place in Australia and around the world to address this new variant.

The Omicron variant has been spreading in Australia and is now the dominant strain of COVID-19. On 22 December 2021, the Australian Health Protection Principal Committee provided a statement on the public health implications of the Omicron variant and response options. These included that current medical evidence indicates the Omicron variant is substantially more transmissible than the Delta variant in populations with a high previous exposure to COVID-19 or high vaccination coverage, with most recent estimates demonstrating that the number of cases are doubling every 2-3 days.

On 6 January 2022, Australia recorded over 72,000 new cases of COVID-19. Increasing cases of COVID-19 result in increasing reliance on state or territory testing facilities and emergency responses. Increasing cases also means that more people are exposed to the virus as close or casual contacts, and are required to get tested, quarantine or monitor for symptoms of COVID-19.

RATs provide an alternative diagnostic tool with faster test result turnaround times in comparison with PCR tests and may be used individually by persons to detect the presence of the virus. The increasing reliance on these tests has reportedly led to some people taking advantage of the pandemic to supply RATs at grossly inflated prices. This measure is therefore designed as part of other non-legislative measures to ensure that there is sufficient supply of RATs in Australia and to deter price-gouging.

As part of these measures, the Australian Competition and Consumer Commission (“ACCC”) has announced that it is aware of the significant public concern about the pricing of RATs and is monitoring the situation very closely for breaches of the Australian Consumer Law (“ACL”) as set out in Schedule 2 of the *Competition and Consumer Act 2010*.

The ACCC released a statement about actions under their existing powers that may be taken in response to this issue on their website on 4 January 2022. The ACCC has advised that it is investigating complaints and will be prepared to take any necessary action, including by identifying businesses who engage in price-gouging. Further, the ACCC has advised that it may take action with respect to false and misleading representations, and unconscionable conduct.

Commencement

The Determination commences on Saturday 8 January 2022 at 1.00am (by legal time in the Australian Capital Territory).

Consultation

The Department of Home Affairs, the Attorney-General’s Department, the Department of Prime Minister and Cabinet, the Australian Competition and Consumer Commission, and the Australian Federal Police were consulted in the making of the Determination.

Attachment

A provision by provision description of the Determination is set out in the Attachment.

Details of the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022*

Part 1—Preliminary

Section 1 provides that the name of the Determination is the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (COVID-19 Rapid Antigen Tests) Determination 2022*.

Section 2 provides that the Determination commences at 1.00am (by legal time in the Australian Capital Territory) on 8 January 2022.

Section 3 states that the authority for making the Determination is subsection 477(1) of the Biosecurity Act.

Section 4 sets out the definitions used in the Determination.

A note at the beginning of section 4 states that a number of expressions used in the Determination are defined in the Biosecurity Act, including the following:

- ***declaration listed human disease***, in relation to a human biosecurity emergency declaration and a human biosecurity emergency period, means the listed human disease specified under paragraph 475(3)(a) of the Biosecurity Act in the human biosecurity emergency declaration that specifies the human biosecurity emergency period.
- ***human biosecurity emergency period*** means the period specified under paragraph 475(3)(c) of the Biosecurity Act in a human biosecurity emergency declaration as the period during which the declaration is in force.
- ***officer of Customs*** has the same meaning as section 4 of the *Customs Act 1901* and includes:
 - (a) the Secretary of the Department; or
 - (b) the Australian Border Force Commissioner (including in his or her capacity as the Comptroller-General of Customs); or
 - (c) an APS employee in the Department; or
 - (d) a person authorised under subsection (1B) to exercise all the powers and perform all the functions of an officer of Customs; or
 - (e) a person who from time to time holds, occupies, or performs the duties of an office or position (whether or not in or for the Commonwealth) specified under subsection (1C), even if the office or position does not come into existence until after it is so specified; or
 - (f) in relation to a provision of a Customs Act:
 - (i) a person authorised under subsection (1D) to exercise the powers or perform the functions of an officer of Customs for the purposes of that provision; or

- (ii) a person who from time to time holds, occupies, or performs the duties of an office or position (whether or not in or for the Commonwealth) specified under subsection (1E) in relation to that provision, even if the office or position does not come into existence until after it is so specified.

ABN in the Determination has the same meaning as in the *A New Tax System (Australian Business Number) Act 1999*.

COVID-19 human biosecurity emergency period means a human biosecurity emergency period if the declaration listed human disease in relation to the period is human coronavirus with pandemic potential.

Note 1 clarifies that COVID-19 is the name given by the WHO to the disease. Note 2 provides that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the name given by the International Committee on Taxonomy of Viruses to the virus that causes the disease.

COVID-19 rapid antigen test kit means a medical device that is a single use lateral flow or immunochromatographic test kit, classified as a Class 3 IVD medical device (within the meaning of the *Therapeutic Goods (Medical Devices) Regulations 2002*); and included in the Register (within the meaning of the *Therapeutic Goods Act 1989*) with an intended purpose, accepted in relation to that inclusion, that relates to the detection of the novel coronavirus SARS-CoV-2 that causes COVID-19.

GST Act means the *A New Tax System (Goods and Services Tax) Act 1999*.

Law enforcement officer in the Determination means one of the following, all within the meaning of the *Australian Federal Police Act 1979*:

- the Commissioner of the Australian Federal Police;
- a Deputy Commissioner of the Australian Federal Police;
- a member of the Australian Federal Police;
- a special member of the Australian Federal Police.

Officer of Customs in the Determination has the same meaning as in the *Customs Act 1901*.

Price gouging is defined in subsection 5(2) of the Determination.

Retail transaction is defined in subsection 5(3) of the Determination.

Part 2—Price Gouging

Section 5 sets out requirements regarding price gouging in relation to COVID-19 rapid antigen test kits.

Subsection 5(1) provides that a person must not engage in price gouging in relation to a COVID-19 rapid antigen test kit.

Subsection 5(2) provides that a person engages in price gouging in relation to a COVID-19 rapid antigen test kit if:

- the person supplies, or offers to supply, the COVID-19 rapid antigen test kit during the COVID 19 human biosecurity emergency period; and
- the person purchased the COVID-19 rapid antigen test kit in a retail transaction; and
- the value of the consideration for which the person supplies, or offers to supply, the COVID-19 rapid antigen test kit is more than 120% of the value of the consideration for which the person purchased the COVID-19 rapid antigen test kit.

Subsection 5(3) provides that, for the purposes of determining whether the person purchased the COVID-19 rapid antigen test kit in a ‘retail transaction’, it is not relevant whether or not, at the time of purchase, the person intended to supply, or offer to supply the COVID-19 rapid antigen test kit. The term ‘retail transaction’ is otherwise intended to be interpreted according to its ordinary meaning, generally meaning transactions that are ‘consumer-facing’ rather than wholesale purchases made by a major supplier or a manufacturer of the goods.

The phrase ‘purchased the COVID-19 rapid antigen test kit in a retail transaction’ ensures that the price gouging provisions will apply to an individual who purchases goods directly from supermarkets, pharmacists, chemists or other retail stores (whether online or in person) and sells them, or offers to sell them, during the relevant biosecurity emergency period at over 120% of the consideration of the value they purchased them for. This also ensures that entities that are integral to maintaining Australia’s supply chains for COVID-19 rapid antigen test kits, including major suppliers (who generally purchase COVID-19 rapid antigen test kits wholesale) and manufacturers of COVID-19 rapid antigen test kits, will not be bound by this prohibition.

Subsection 5(4) provides that for the purposes of paragraph 5(2)(c), so much of the value of the consideration for which the person supplies, or offers to supply, the COVID-19 rapid antigen test kit as is directly attributable to costs reasonably incurred by the person in transporting or delivering the test kit should be disregarded. This ensures that small remote stores, who may purchase their COVID-19 rapid antigen test kits at retail and transport them long distances, will not be negatively affected.

Section 6 sets out the requirement not to dispose of, or deal with, COVID-19 rapid antigen test kits.

Subsection 6(1) provides that, subject to section 7, a person must not dispose of, or deal with, a COVID 19 rapid antigen test kit if a law enforcement officer has notified the person, in writing, and this notice has not been withdrawn that:

- the officer suspects on reasonable grounds that the person has engaged, is engaging or intends to engage in price gouging in relation to the test kit; and
- the person is required not to dispose of, or deal with, the test kit; and

- the notice will be withdrawn if the person satisfies a law enforcement officer on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the test kit.

Subsection 6(2) provides that, if a person has been notified as above in relation to a COVID-19 rapid antigen test kit, a law enforcement officer must withdraw the notice, in writing, if the law enforcement officer is satisfied on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the COVID-19 rapid antigen test kit.

A person could satisfy a law enforcement officer of this on reasonable grounds, for example, by providing a receipt, financial record of a transaction or other compelling information demonstrating that the consideration for the sale was not more than 120% of the value of consideration for the retail purchase price, that the price can be justified with reference to transport or delivery prices or that the goods were purchased wholesale or were manufactured. Once the notice is withdrawn, the person will be permitted to dispose of, or deal with, the COVID-19 rapid antigen test kit again.

Section 7 sets out the requirement to surrender COVID-19 rapid antigen test kits.

Subsection 7(1) provides that a person must surrender a COVID-19 rapid antigen test kit to a law enforcement officer if the officer notifies the person, in writing, that:

- the law enforcement officer suspects on reasonable grounds that the person has engaged, is engaging or intends to engage in price gouging in relation to the COVID-19 rapid antigen test kit; and
- the person is required to surrender the COVID-19 rapid antigen test kit to the law enforcement officer; and
- the goods will be destroyed or given away after 21 days unless the person satisfies a law enforcement officer on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price-gouging in relation to the COVID-19 rapid antigen test kit.

Subsection 7(2) provides that the requirements outlined in subsections 7(3) and 7(4) apply to a law enforcement officer where a person surrenders COVID-19 rapid antigen test kits under subsection 7(1).

Subsection 7(3) requires a law enforcement officer to return the COVID-19 rapid antigen test kit to the person as soon as practicable if:

- the law enforcement officer is satisfied on reasonable grounds that the person has not engaged, is not engaging, and does not intend to engage in price gouging in relation to the COVID-19 rapid antigen test kit; and
- the COVID-19 rapid antigen test kit has not been destroyed or given away under subsection 7(4).

This effectively gives a person 21 days from the date of surrender to provide information that they have not engaged in, and do not intend to engage in, price gouging. A person could satisfy an officer of this on reasonable grounds, for example, by providing a receipt, financial record of a transaction or other compelling

information demonstrating that the consideration for the sale was less than 120% more than the value of the consideration for the purchase, that the price can be justified with reference to transport or delivery prices, or that the COVID-19 rapid antigen test kit was purchased wholesale or manufactured. Once the COVID-19 rapid antigen test kit has been returned, a person will be able to deal with the COVID-19 rapid antigen test kit again.

Subsection 7(4) provides that a law enforcement officer must do the following as soon as practicable if, 21 days after the person surrenders the COVID-19 rapid antigen test kit, the law enforcement officer is not satisfied on reasonable grounds that the person has not engaged, is not engaging and does not intend to engage in price gouging in relation to the COVID-19 rapid antigen test kit:

- destroy the COVID-19 rapid antigen test kit if the law enforcement officer believes on reasonable grounds that:
 - the COVID-19 rapid antigen test kit is defective; or
 - there is a risk that that the COVID-19 rapid antigen test kit is defective and because of that risk, the COVID-19 rapid antigen test kit should not be used.
- otherwise – give the COVID-19 rapid antigen test kit to the National Medical Stockpile.

Part 3—Export restrictions

Section 8 provides that subject to section 9, a person must not export a COVID-19 rapid antigen test kit from Australia during the COVID-19 human biosecurity emergency period.

Section 9 provides for exceptions to the restrictions on the export of COVID-19 rapid antigen test kits during the COVID-19 human biosecurity emergency period.

Subsection 9(1) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply to a COVID-19 rapid antigen test kit if it is accompanied personal or household effects of a person who is either a passenger on or a crew member of a ship or aircraft, if the COVID-19 rapid antigen test kits are for the personal use of the person.

This means that, for example, a person who boards a ship or aircraft that is departing overseas may export a COVID-19 rapid antigen test kit for their personal use.

Subsection 9(2) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply to a COVID-19 rapid antigen test kit if it is exported by a person to a relative of the person, for the relative's personal use, and the exportation is not by post.

This means that, for example, a person may send a care package containing a COVID-19 rapid antigen test kit for the relative's use.

Subsection 9(3) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply to a COVID-19 rapid antigen test kit if the test kit is intended for an employee of the person, and for the employee's personal use and the test kit is not exported via post.

Subsection 9(4) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply to a COVID-19 rapid antigen test kit if it is exported by a humanitarian organisation or agency, and the export is not for commercial purposes and is not exported via post.

Subsection 9(5) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply if they are exported by a person who manufactured the goods, and the goods are exported other than by post.

This means, for example, that the restriction on the export of a COVID-19 rapid antigen test kit does not apply to COVID-19 rapid antigen test kits that an Australian company manufactures. However, if the same COVID-19 rapid antigen test kits were to be exported by post, their export is restricted.

Subsection 9(6) provides that the restriction on the export of a COVID-19 rapid antigen test kit does not apply if a person exporting a COVID-19 rapid antigen test kit:

- exports it in the ordinary course of the person's business; and

- the person is registered under the *A New Tax System (Goods and Services Tax) Act 1999* and has an ABN; and
- the exportation is not by post.

This means, for example, the restriction on the export of a COVID-19 rapid antigen test kit does not apply to COVID-19 rapid antigen test kits exported by a company that has operated a business of exporting (but not manufacturing) COVID-19 rapid antigen test kits, by air cargo, and who is registered for GST and has an ABN.

Section 10 sets out the requirement to surrender COVID-19 rapid antigen test kits to an officer of Customs.

Subsection 10(1) provides that section 10 applies to a person who attempts to export a COVID-19 rapid antigen test kit during the COVID-19 human biosecurity emergency period and the COVID-19 rapid antigen test kit is in the possession of an officer of Customs and the export of the COVID-19 rapid antigen test kit under section 8 applies.

Subsection 10(2) provides that a person must surrender the COVID-19 rapid antigen test kit to an officer of Customs if the officer notifies the person, in writing, that the person is required to surrender the COVID-19 rapid antigen test kit.

Subsection 10(3) provides that if the person surrenders the COVID-19 rapid antigen test kit under subsection 10(2), an officer of Customs must do as soon as practicable:

- destroy the COVID-19 rapid antigen test kit if the officer of Customs believes on reasonable grounds that:
 - the COVID-19 rapid antigen test kit is defective; or
 - there is a risk that that the COVID-19 rapid antigen test kit is defective and because of that risk, the COVID-19 rapid antigen test kit should not be used; or
- otherwise – give the COVID-19 rapid antigen test kit to the National Medical Stockpile.