

EXPLANATORY STATEMENT

Issued by the Minister for Home Affairs

Customs Act 1901

Customs Legislation Amendment (Vaping Goods) Regulations 2023

Legislative authority

The *Customs Act 1901* (Customs Act) concerns customs related functions and is the legislative authority that sets out the customs requirements for the importation and exportation of goods to and from Australia.

Subsection 270(1) of the Customs Act provides, in part, that the Governor-General may make regulations not inconsistent with the Customs Act prescribing all matters, which by the Customs Act are required or permitted to be prescribed or as may be necessary or convenient to be prescribed for giving effect to the Customs Act.

Section 50 of the Customs Act provides, in part, that the Governor-General may, by regulation, prohibit the importation of goods into Australia and that the power may be exercised by prohibiting the importation of goods absolutely or by prohibiting the importation of goods unless specified conditions or restrictions are complied with.

For section 50 of the Customs Act, the *Customs (Prohibited Imports) Regulations 1956* (Prohibited Imports Regulations) control the importation into Australia of certain goods by prohibiting importation absolutely, or by making importation subject to a permission or licence.

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws) the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend or vary any such instrument.

Purpose

The *Customs Legislation Amendment (Vaping Goods) Regulations 2023* (Amendment Regulations) amend the Prohibited Imports Regulations to establish import control for vapes, vape substances and vape accessories, collectively described as ‘vaping goods’.

The import control for vaping goods is achieved through new regulation 5A, which limits the circumstances under which those goods can be imported into Australia.

Background

Vaping in Australia has increased dramatically in recent years. This poses a major risk to population health and threatens to disrupt the significant achievements that Australia has made in tobacco control to date. Research suggests that vaping is a gateway to smoking.

Vaping mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely. Never-smokers who vape are approximately three times more likely to take up cigarette smoking than those who do not vape. Further, there is substantial evidence that vaping results in dependence, and causes respiratory disease, severe burns, nicotine poisoning and seizures. The long-term health effects of vaping are not known.

The Amendment Regulations are intended to address the risks posed by vaping to children and young people in Australia, while preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine addiction.

Impact and effect

The Amendment Regulations insert new regulation 5A into the Prohibited Imports Regulations, which restricts the lawful importation of vapes to those that are included in the Australian Register of Therapeutic Goods; those for which the importer has notified the Secretary of the Department of Health and Aged Care that the vape is compliant with relevant quality standards; and vapes that are only for medical or scientific research. Importers are required to obtain a licence and permit to import such products under new regulation 5A.

The Amendment Regulations also introduce an authority for the Minister administering the *Therapeutic Goods Act 1989* to approve the importation of other vaping goods in a legislative instrument if the goods meet one or more of the criteria specified in new regulation 5A, and authorises the Secretary to specify, by legislative instrument, purposes for which vaping goods may be imported and kinds of vaping goods that may be imported.

Importation is prohibited absolutely in the post with the effect that vaping goods may only enter Australia as cargo or with travellers. New regulation 5A allows international travellers to import limited quantities of vaping goods for personal use in connection with treatment.

The Amendment Regulations also amend the *Customs Regulation 2015* (Customs Regulation) to prescribe vaping goods for the purposes of section 209M of the Customs Act, and to permit the surrender of these goods to an officer of Customs in a place used by those officers for questioning passengers or crew disembarking from a ship or aircraft, as described in section 234AA of the Customs Act.

Consultation

The Department of Home Affairs developed these import controls, at the request of the Department of Health and Aged Care, to support the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* developed by the Department of Health and Aged Care.

The Therapeutic Goods Administration (TGA) conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation (the 2022 consultation) on reforms to the regulation of nicotine vaping products in Australia, including a proposal to strengthen border controls by requiring importers to obtain an import permit and by closing off the personal importation scheme. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023, which conveyed Ministers' collective commitment to enhancing regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 (the 2023 Consultation) on the regulatory proposals developed in consultation with the states and territories. Submissions and survey responses to the 2023 Consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for the Department of Health and Aged Care on regulatory measures to be implemented (including those that are to be implemented in these Amendment Regulations).

On 10 October 2023, the Office of Impact Analysis (OIA) assessed the Impact Analysis for the reforms for the regulation of vaping products as 'good practice'. The Impact Analysis will be published by OIA following the Amendment Regulations being made.

Details and operations

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Regulations commence at the same time as the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*.

Details of the Amendment Regulations are set out in Attachment A.

Other

The Amendment Regulations are compatible with the human rights and freedoms recognised or declared in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full Statement of Compatibility with Human Rights is set out in Attachment B.

Division 1 of Part 3 of Chapter 3 of the Legislation Act operates to automatically repeal a legislative instrument that has the sole purpose of amending or repealing another instrument. That Division applies to automatically repeal the Amendment Regulations. As the Amendment Regulations will be automatically repealed, the sunseting framework under Part 4 of the Legislation Act is not engaged.

Details of the Customs Legislation Amendment (Vaping Goods) Regulations 2023

Section 1 – Name

This section provides that the title of the Regulations is the *Customs Legislation Amendment (Vaping Goods) Regulations 2023* (Amendment Regulations).

Section 2 – Commencement

This section sets out, in a table, the date on which each of the provisions contained in the Amendment Regulations commence.

Table item 1 has effect that the Amendment Regulations commence at the same time as the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*. However, the provisions of the Amendment Regulations do not commence at all if that instrument does not commence.

The note below the table provides that the table relates only to the provisions of the Amendment Regulations as originally made. It will not be amended to deal with later amendments of the Amendment Regulations. The purpose of this note clarifies that the commencement of any subsequent amendments will not be reflected in this table.

Section 3 – Authority

This section provides that the Amendment Regulations are made under the *Customs Act 1901* (Customs Act).

Section 4 – Schedules

This section sets out the formal enabling provision for the Schedules to the Amendment Regulations, and provides that each instrument 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.

The Amendment Regulations amend the *Customs (Prohibited Imports) Regulations 1956* (Prohibited Imports Regulations) and the *Customs Regulation 2015* (Customs Regulation).

Schedule 1—Amendments

Customs (Prohibited Imports) Regulations 1956

The purpose of the amendments to the Prohibited Imports Regulations is to introduce new import controls for all **vapes** and **vape accessories**, and **vape substances** (collectively defined as **vaping goods** (see item [1] of the Amendment Regulations), in particular new subregulation 5A(19)), irrespective of the type of device or whether the product includes nicotine or makes a claim for therapeutic purposes.

Key elements of the new import prohibition are explained below.

Item 1 After regulation 5

This item introduces a new regulation 5A to impose a prohibition on the importation of **vaping goods**, establishes clear exemptions from the prohibition, introduces a licencing and permission scheme for importation of **vaping goods**, and introduces new definitions.

Importation of vaping goods

New subregulation 5A(1) – Prohibitions on importation of vaping goods

New paragraph 5A(1)(a) has the effect that, subject to new subregulations 5A(2) to (4), the importation into Australia of **vaping goods** is prohibited unless:

- the person importing the **vaping goods** is the holder of both a licence to import the **vaping goods** granted by a **prescribed authority** under this regulation (new subparagraph 5A(1)(a)(i)); and
- a permission to import the **vaping goods** granted by a **prescribed authority** under this regulation (new subparagraph 5A(1)(a)(ii)).

The purpose of paragraph 5A(1)(a) is to prohibit the import of vaping goods unless the importer holds both a licence to import **vaping goods** and permission to import **vaping goods**, that was granted by a **prescribed authority** under this regulation, if none of the exemptions to this prohibition in new subregulations 5A(2) to (4) apply.

New paragraph 5A(1)(b) has the effect that the permission, or a copy of the permission, must be produced to the collector. The term ‘collector’ is defined in subsection 8(1) of the Customs Act to mean a reference to the Comptroller-General of Customs, or any officer doing duty in the matter in relation to which the expression is used. The purpose of new paragraph 5A(1)(b) is to ensure the integrity of the licencing and permission scheme.

New paragraph 5A(1)(c) has the effect that importations by post are prohibited absolutely irrespective of whether or not the importer has a licence and permission to import **vaping goods**. The purpose of new paragraph 5A(1)(c) is to enable regulatory oversight in the administration of the importation of **vaping goods** by effectively requiring importations to be made via the cargo stream. This facilitates more oversight by the Australian Border Force of any importations of **vaping goods**.

The note at the end of new subregulation 5A(1) reminds the reader that a number of expressions used in this regulation is defined in new subregulation 5A(19), including **disposable vape, vape, vape accessory, vape substance** and **vaping goods**.

The purpose of new subregulation 5A(1) is to impose import controls over vaping goods, prohibiting the importation of such goods unless the importer holds a licence and permission or a new subregulation 5A(2), (3) or (4) exemption from the requirement to hold a licence and permission applies.

This amendment is consistent with paragraph 50(3)(a) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), the regulations may provide that the importation of the goods is prohibited unless a licence, permission, consent or approval to import the goods or a class of goods in which the goods are included has been granted as prescribed by the regulations made under this Act or the *Therapeutic Goods Act 1989*.

New subregulations 5A(2) to (4)

New subregulations 5A(2) to (4) specifies exemptions to the prohibition on the importation into Australia of **vaping goods** set out in new subregulation 5A(1).

Importation by travellers

New subregulation 5A(2)

New subregulation 5A(2) exempts certain persons on board a ship or aircraft ('travellers') from the prohibition in new subregulation 5A(1), and in effect, do not require the importer to hold a licence or permission to import.

New paragraph 5A(2)(a) has the effect that new subregulation 5A(1) does not apply to the importation of **vaping goods** by a person who is on board a ship or aircraft, if the **vaping goods** are presented by the person as being for use in connection with the treatment of the person importing the **vaping goods**, or for use in connection with the treatment of one or more persons on board the ship or aircraft who is under the care of the importer.

It should be noted that goods may be presented for use in connection with the treatment of a person without the goods having being prescribed and without the goods being for purposes relating to smoking cessation.

The exemption for travellers is an acknowledgment of the fact that most countries treat vaping goods as consumer goods and that travellers from those countries may consider vaping substances, including substances such as melatonin and vitamins, to be therapeutic and able to be self-prescribed.

New paragraph 5A(2)(b) has the effect that the exemption under new subregulation 5A(2) does not apply to the importation of **vaping goods** by a person who is on board a ship or aircraft, if the **vaping goods** imported: consist of no more than two **vapes** (new subparagraph 5A(2)(b)(i)) per person; and **vaping goods** that consist of no more than 20 vaping cartridges, capsules or pods (new subparagraph 5A(2)(b)(ii)) per person; and 200 ml of liquid (new subparagraph 5A(2)(b)(iii)) per person.

For example:

A person on board a ship may be the carer of two other persons, also on board the ship. Each of the three individuals have vapes and vape substances. Each person (carer and persons under their care) may have two vapes of the disposable type or two vapes of the reusable type, or one vape of the disposable type and one vape of the reusable/ type (i.e., two devices in total per person). In addition:

- Person A (carer) has 1 disposable and 1 reusable vape, and 200 ml of vaping liquid
- Person B (person under Person A's care) 2 reusable vapes, 15 cartridges and 190 ml of vaping liquid
- Person C (person under Person A's care) 2 disposable vapes.

The quantities of **vapes** and **vape substances** in the above example would be within the prescribed limits of the exemption in this subregulation. Similarly, if Person B had 2 reusable **vapes**, 6 cartridges, 8 capsules and 4 pods and 2 x 95 ml bottles of vaping liquid, this would be within the limits.

Alternatively, if Person B had 3 reusable **vapes**, 10 cartridges, 8 capsules and 6 pods and 2 x 120 ml bottles of vaping liquid for use in the second or third reusable **vape**, this would not be within the prescribed limits.

Importation permitted under new paragraphs 5(1)(a) to (d) or paragraph 5(2)(b)

New subregulation 5A(3)

Goods

New paragraph 5A(3)(a) provides an exemption to the prohibition in new subregulation 5A(1), and expressly permits the importation of goods without a regulation 5A licence or permission if the goods are already subject to licencing and permission requirements set out in paragraphs 5(1)(a), (b), (c) or (d) of the Prohibited Imports Regulations or the ‘traveller exemption’ in paragraph 5(2)(b) of those Regulations, which deal with the importation of prohibited drugs specified in Schedule 4 to the Prohibited Imports Regulations.

An example of a Schedule 4 drug that would require a regulation 5 permission, but would not also require a regulation 5A permission, is cannabis oil (see table item 35 of Schedule 4 to the Prohibited Imports Regulations).

New paragraph 5A(3)(a) deals expressly with the goods imported. The purpose of this paragraph is to make clear that goods that are already subject to the specified regulation 5 licencing and permission requirements will not be treated as **vaping goods** for the purposes of new regulation 5A, and are therefore exempt from the new subregulation 5A(1) requirements. If an exemption did not apply to these goods, they could otherwise meet the definition of **vapes**, **vaping substances** and **vaping accessories**.

Disposable devices and accessories

New paragraph 5A(3)(b) provides an exemption to the prohibition in new subregulation 5A(1), for **disposable vapes** or **vape accessories** if the substances the **disposable vapes** or **vape accessories** contain are goods that are already subject to licencing and permission requirements set out in paragraphs 5(1)(a), (b), (c) or (d) of the Prohibited Imports Regulations or paragraph 5(2)(b) of those Regulations.

New paragraph 5A(3)(b) deals expressly with the disposable devices and any capsule, cartridge, pod or bottle that contain substances that are already subject to licencing and permission requirements set out in paragraphs 5(1)(a), (b), (c) or (d) of the Prohibited Imports Regulations or the ‘traveller exemption’ set out in paragraph 5(2)(b) of those Regulations. If an exemption did not apply to these goods, they would otherwise meet the definition of **disposable vape** and **vaping accessories**, respectively.

This amendment is consistent with subparagraph 50(3)(b)(i) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), the regulations in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the assignment of licences or permissions so granted or of licences or permissions included in a prescribed class of licences or permissions so granted.

Importation permitted under a subsection 5A(5) approval

New subregulation 5A(4)

New subregulation 5A(4) provides an exemption to the prohibition in new subregulation 5A(1), if the Minister has approved the importation under new subregulation 5A(5).

This subregulation expressly permits the importation of **vaping goods** without a regulation 5A licence or permission if the importation of the goods has been approved by the Minister in a legislative instrument made under new subregulation 5A(5).

The purpose of this provision is to ensure that certain goods can be approved for importation where they do not meet the criteria to obtain a permit. This could be used to approve:

- importations of vapes by military and sporting groups and heads of state;
- importations for law enforcement purposes.

It is also possible that as new medicines and medical devices enter the market that involve the inhalation of medicines, they could fall within the relevant definitions of vaping goods despite not being related to vaping within the ordinary meaning of the word. This provision allows such goods to be imported without requiring amendments to the permit criteria, which ensures that the timely availability of such goods in Australia is not unduly compromised.

This amendment is consistent with subparagraph 50(3)(b)(i) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), the regulations in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the assignment of licences or permissions so granted or of licences or permissions included in a prescribed class of licences or permissions so granted.

Minister may approve importation without a licence or permit

New subregulation 5A(5)

New subregulation 5A(5) provides the Minister with the discretion to approve in a legislative instrument the importation into Australia of **vaping goods**.

This discretion may be exercised in circumstances where the **vaping goods** satisfy one or more of the following criteria – if the **vaping goods**:

- are specified in, or included in a class of **vaping goods** specified in, the approval (new paragraph 5A(5)(a));
- are imported in a form (including a concentration) specified in the approval (new paragraph 5A(5)(b));

- are imported by a person, or class of persons, specified in the approval (new paragraph 5A(5)(c));
- do not exceed a value or amount specified in the approval (new paragraph 5A(5)(d));
- are imported in a way, or by a means, specified in the approval (new paragraph 5A(5)(e)).

The purpose of this provision is to ensure that certain goods can be approved for importation where they do not meet the criteria to obtain a permit. This could be used to approve:

- importations of **vapes** by military and sporting groups and heads of state;
- importations for law enforcement purposes.

It is also possible that as new medicines and medical devices enter the market that involve the inhalation of medicines, they could fall within the relevant definitions despite not being related to vaping within the ordinary meaning of the word. The discretion to approve the importation into Australia of **vaping goods** would allow such goods to be imported without requiring licences and permits.

It is important to note that a legislative instrument made by the Minister for the purposes of new subregulation 5A(5) would be a disallowable legislative instrument, and therefore subject to parliamentary scrutiny.

This amendment is consistent with subparagraph 50(3)(b)(i) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), the regulations in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the assignment of licences or permissions so granted or of licences or permissions included in a prescribed class of licences or permissions so granted.

Applications for licences and permissions

New subregulation 5A(6)

New subregulation 5A(6) provides that an applicant for a licence or a permission to import **vaping goods** must:

- make the application on the form approved by the **Secretary** (new paragraph 5A(6)(a)); and
- lodge the application with a **prescribed authority**, defined in subregulation 5A(19), (new paragraph 5A(6)(b)); and
- give to the **prescribed authority** any information that the **prescribed authority** reasonably requires for the purpose of making a decision on the application (new paragraph 5A(6)(c)).

The effect of this subregulation is to set out how, and to whom, an application must be made, and to stipulate that the application includes any information that is reasonably required for making a decision to grant or refuse permission.

‘Reasonably required’ in this subregulation has the meaning that the information is relevant to the applicant, the business the applicant operates or the research they conduct, and the **vaping goods** the applicant seeks a licence and permission to import, and that it is ‘reasonable’ of the **prescribed authority** to require this information in order to make a fully informed decision.

Dealing with applications for licences

New subregulation 5A(7)

New subregulation 5A(7) provides that a **prescribed authority** must not grant to an applicant a licence to import **vaping goods** unless:

- the applicant has given the **prescribed authority** all the information required by the **prescribed authority** under new paragraph 5A(6)(c) (new paragraph 5A(7)(a)); and
- the **prescribed authority** is satisfied that the applicant is to import the **vaping goods**:
 - for **vaping goods** other than **disposable vapes**—for the purposes of manufacture and supply as part of the applicant’s business or only for the purposes of supply or use in medical or scientific research (new subparagraph 5A(7)(b)(i)); or
 - for **disposable vapes**—only for the purpose of supply or use for medical or scientific research (new subparagraph 5A(7)(b)(ii)); and
- the applicant is registered for **GST** (new paragraph 5A(7)(c)); and
- the applicant has an **ABN** (new paragraph 5A(7)(d)); and
- if the applicant is required, under a law of a State or Territory in which the applicant operates the business, to hold a licence or other approval or permission (however called) in relation to the **vaping goods**—the applicant holds the relevant licence or approval (new paragraph 5A(7)(e)).

It is important to note that the licence referred to in new subregulation 5A(7) must be granted before importation, and see also new subregulation 5A(12), which requires permission to import be granted before importation. In practice, a person must be granted a licence to import, and then permission to import, before they can lawfully import **vaping goods**.

New paragraph 5A(7)(a) prohibits the **prescribed authority** from granting a licence unless all of the information, reasonably required under paragraph 5A(6)(c) in order to make a fully informed decision, has been provided to the **prescribed authority**.

New subparagraph 5A(7)(b)(i) prohibits the **prescribed authority** from granting a licence unless satisfied that the entity is intending to sell **vaping goods** that are not **disposable vapes** for the purposes of manufacture and supply as part of the entity’s business, or for medical or scientific research.

New subparagraph 5A(7)(b)(ii) prohibits the **prescribed authority** from granting a licence unless satisfied that the entity is intending to import **disposable vapes** for use and supply for medical or scientific research.

New paragraph 5A(7)(c) prohibits the **prescribed authority** from granting a licence unless satisfied that the importer has an **ABN** (Australian Business Number), this is defined in new subregulation 5A(19) as having the same meaning given by section 41 of the *A New Tax System (Australian Business Number) Act 1999*.

New paragraph 5A(7)(d) prohibits the **prescribed authority** from granting a licence unless satisfied that the importer is registered for **GST** (Goods and Sales Tax), this is defined in new subregulation 5A(19) as meaning registered under the GST Act.

New paragraph 5A(7)(e) prohibits the **prescribed authority** from granting a licence unless satisfied, if the importer is required to hold a State or Territory licence or other approval (however the ‘approval’ is described) in the State or Territory they conduct their business, that the entity does hold the relevant licence or other approval before a licence to import can be granted.

The purpose of this subregulation is to act as a limit on the power of a **prescribed authority** to grant or refuse to grant a licence to import **vaping goods**, and to set out the circumstances under which an application for a licence must be refused. It is important to note that the licencing scheme under new regulation 5A is administered by the **Secretary** of the Department of Health and Aged Care and officers of that **Department** authorised by the **Secretary**.

In practice, new subsection 5A(7) will mirror the current administrative arrangements for a licence under regulation 5 of the Prohibited Imports Regulations, which ensures consistency and expediency in the regulatory administration of the importation of **vaping goods** under new regulation 5A.

New subregulation 5A(8)

New subregulation 5A(8) has the effect that, in considering whether to grant a licence, the **prescribed authority** may consider any relevant matter.

The purpose is to ensure that the prescribed authority is not limited to considering the matters in new subregulation 5A(7), and is able to consider the overall suitability of an applicant is considering whether to grant a licence.

An example of a ‘relevant matter’ would be the suitability of the applicant to hold a licence to import **vaping goods**. This could include matters relating to propriety, such as previous criminal convictions.

Conditions of licences

New subregulation 5A(9)

New subregulation 5A(9) provides that a licence may specify conditions or requirements to be complied with by the holder of the licence (new paragraph 5A(9)(a)), and when the holder must comply with a condition or requirement, whether before or after the importation of the **vaping goods** to which the licence relates (new paragraph 5A(9)(b)).

An example of a condition that may be imposed is that the licence holder must have secure premises in which **vaping goods** can be stored.

The purpose of this subregulation is to provide the prescribed authority with discretion to impose conditions on licences granted to importers for the importation of vaping goods.

This amendment is consistent with subparagraph 50(3)(b)(ii) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the granting of a licence or permission to import goods subject to compliance with conditions or requirements, either before or after the importation of the goods, by the holder of the licence or permission at the time the goods are imported.

New subregulation 5A(10)

New subregulation 5A(10) has the effect that a licence to import a **disposable vape** is, in addition to any condition specified in the licence under new subregulation 5A(9), subject to the condition that the device must only be used for the purposes of supply or use for medical or scientific research.

The purpose of this provision is to ensure that **disposable vapes** are not made available for general supply in the community. **Disposable vapes** are preferred by children and adolescents due to their low cost and ease of concealment from parents and teachers, and are damaging to the environment. It is therefore important that their uses be limited to medical or scientific research.

This amendment is consistent with subparagraph 50(3)(b)(ii) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the granting of a licence or permission to import goods subject to compliance with conditions or requirements, either before or after the importation of the goods, by the holder of the licence or permission at the time the goods are imported.

Revocation of licences

New subregulation 5A(11)

New subregulation 5A(11) provides that, if a licence to import **vaping goods** specifies a condition or requirement to be complied with by the holder of the licence (new paragraph 5A(11)(a)), and the holder of the licence fails to comply with the condition or requirement (new paragraph 5A(11)(b)), the **Secretary** or an **authorised officer** may revoke the licence, whether or not the holder of the licence is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

New subregulation 5A(11) deals with the circumstances in which the **Secretary** or an **authorised officer** may revoke the licence to import **vaping goods**, whether or not the holder of the licence is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

New subregulation 5A(11) is authority for revocation of licence to import **vaping goods** if a licence to import **vaping goods** specifies a condition or requirement to be complied with by the holder of the permission (new paragraph 5A(11)(a)) and the holder of the licence fails to comply with the condition or requirement new paragraph 5A(11)(b).

In those circumstances, the **Secretary** or an **authorised officer** may, in writing, revoke the permission, irrespective of whether or not the holder of the permission is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

An example would be where a licence holder is convicted of a criminal offence if not having a criminal record is a condition, or where a licence holder imports **vaping goods** that do not comply with applicable standards under the *Therapeutic Goods Act 1989* if compliance with those standards is a condition.

This amendment is consistent with subparagraph 50(3)(b)(iv) of the Customs Act, which provides that without limiting the generality of paragraph 50(2)(c), in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the revocation of a licence or permission that is granted subject to a condition or requirement to be complied with by a person for a failure by the person to comply with the condition or requirement, whether or not the person is charged with an offence against subsection 50(4) in respect of the failure.

Dealing with applications for permissions

New subregulation 5A(12)

New paragraph 5A(12)(a) provides that a **prescribed authority** must not grant to an applicant a permission to import **vaping goods**, unless the applicant is the holder of a licence granted under new subregulation 5A(1).

As noted above, an entity can only lawfully import **vaping goods** if they hold the relevant licence granted under new subregulation 5A(1) and have been granted permission to import **vaping goods** under new subregulation 5A(12).

New paragraph 5A(12)(b) provides that a permission to import **vaping goods** may only be granted if one or more of the following also apply:

- the **vaping goods** are included in the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act 1989* (new subparagraph 5A(12)(b)(i));
- the **vaping goods** meet the notification requirements in new subregulation 5A(13) (new subparagraph 5A(12)(b)(ii));
- the **vaping goods** are to be imported only for the purposes of supply or use in medical or scientific research (new subparagraph 5A(12)(b)(iii)) and a notice, in a form approved in writing by the **Secretary**, has been given to the **Secretary** stating that the goods are being imported only for that purpose;
- the **vaping goods** are to be imported for a purpose specified for the goods by the **Secretary** under subregulation 5A(14) and a notice, in a form approved in writing by the **Secretary**, has been given to the **Secretary** stating that the goods are being imported only for a purpose specified for the goods (new subparagraph 5A(12)(b)(iv)); and
- the **vaping goods** are **vaping goods** of a kind specified by the **Secretary** under new subregulation 5A(15) (new subparagraph 5A(12)(b)(v)).

The purpose of this subregulation is to act as a limit on the power of a **prescribed authority** to grant or refuse to grant permission to import **vaping goods**, and to set out the circumstances under which an application for permission may be granted. It is important to note that the permission scheme in new regulation 5A is also administered by the **Secretary** of the Department of Health and Aged Care and officers of that **Department** authorised by the **Secretary**.

In practice, new subregulation 5A(12) will mirror the current administrative arrangements for permission to import under regulation 5 of the Prohibited Imports Regulations, which ensures consistency and expediency in the regulatory administration of the importation of vaping goods under new regulation 5A.

Notification requirements

New subregulation 5A(13)

New subregulation 5A(13) deals with the notification requirements for **vaping goods**.

Therapeutic cannabis vapes

New subparagraph 5A(13)(a)(i) has the effect that, for the purposes of subparagraph (12)(b)(ii), a **vaping good** that is a **therapeutic cannabis vaping good** within the meaning of the *Therapeutic Goods (Medical Devices) Regulations 2002* meets the notification requirements of this subregulation if a notice, in a form approved by the **Secretary**, has been given to the **Secretary** stating that the device complies with the essential principles (within the meaning of the *Therapeutic Goods Act 1989*).

New subparagraph 5A(13)(a)(ii), is an alternative to paragraph 5A(13)(a)(i), and has the effect that, for the purposes of subparagraph 5A(12)(b)(ii), a **vaping good** that is a **therapeutic cannabis vaping good** within the meaning of the *Therapeutic Goods (Medical Devices) Regulations 2002* meet the notification requirements of this subregulation if a notice, in a form approved by the **Secretary**, has been given to the **Secretary** stating that the device is imported with the consent of the **Secretary** under section 41MA or 41MAA of *Therapeutic Goods Act 1989*.

Notification requirements specific to these types of goods are necessary because the general notification requirements for **vapes** do not apply to **vapes** that contain or are intended for use with substances containing cannabis, or **vape accessories** for such vapes.

Other vaping goods

New paragraph 5A(13)(b) deals with the notification requirements for any other **vaping goods**.

New subparagraph 5A(13)(b)(i) has the effect that, for the purposes of new subparagraph 5A(12)(b)(ii), **vaping goods** meet the notification requirements of this subregulation if a notice in relation to the **vaping goods** has been given in accordance with paragraph (a) of the column headed “Conditions” of item 2.17 of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*.

New subparagraph 5A(13)(b)(ii) has the effect that, for the purposes of new subparagraph 5A(12)(b)(ii), **vaping goods** meet the notification requirements of this subregulation if a notice in relation to the **vaping goods** has been given in accordance with paragraph (a) of item 2.18 of Part 2 of Schedule 4 to the *Therapeutic Goods Regulations 1990*.

New subparagraph 5A(13)(b)(iii) has the effect that, for the purposes of new subparagraph 5A(12)(b)(ii), **vaping goods** meet the notification requirements of this subregulation if a notice in relation to the vaping goods has been given in accordance with paragraph (a) of column 3 of item 15 of Schedule 5A to the *Therapeutic Goods Regulations 1990*.

New subparagraph 5A(13)(b)(iv) has the effect that, for the purposes of new subparagraph 5A(12)(b)(ii), **vaping goods** meet the notification requirements of this subregulation if a notice in relation to the vaping goods has been given in accordance with paragraph (a) of column 3 of item 16 of Schedule 5A to the *Therapeutic Goods Regulations 1990*.

New paragraph 5A(13)(b) will require a **vaping good**, other than a cannabis **vape** or a cannabis **vape accessory**, to provide a notification to the Secretary that it complies with relevant requirements specified in the *Therapeutic Goods Regulations 1990* or the *Therapeutic Goods Regulations (Medical Devices) Regulations 2002* in order to obtain a permit.

The requirements in those Regulations vary depending on whether the good is for use in the manufacture of a therapeutic good or is a finished good. A **vaping good** that is to be imported for use in the manufacture of a therapeutic good must make a notification to that effect. Other **vaping goods** are only eligible to make a notification if their only use is in connection with smoking cessation or the management of nicotine dependence and the importer intends the goods to be supplied to the ultimate consumer of the goods in accordance with an approval or authority under section 19 of the *Therapeutic Goods Act 1989*. The notification must state that the goods either comply with applicable standards under the *Therapeutic Goods Act 1989* or are imported with consent not comply with such requirements, and that the only use of the goods is in connection with smoking cessation or the management of nicotine dependence.

New subregulation 5A(14)

New subregulation 5A(14) has the effect that the **Secretary** may, by legislative instrument, specify purposes for the purposes of new subparagraph 5A(12)(b)(iv) of this regulation. The **Secretary** may specify a purpose only if the **Secretary** is satisfied that the purpose is not inconsistent with the objects of the *Therapeutic Goods Act 1989*.

The purpose is to ensure that goods that fall within the definition of vaping goods and would not meet the criteria for a permit under new subregulation 5A(12) can obtain a permit where the goods are for legitimate purposes unrelated to vaping.

New subregulation 5A(15)

New subregulation 5A(15) has the effect that the **Secretary** may, by legislative instrument, specify kinds of **vaping goods** for the purposes of subparagraph 5A(12)(b)(v).

Any solution that contains nicotine, in any concentration, will be a **vape substance**. There may be goods that will satisfy this definition despite not being intended for use with a **vape**. Where such goods have a legitimate use unrelated to vaping, but also have the potential to be diverted for use in the manufacture of non-therapeutic vapes, it is appropriate that they be eligible for importation pursuant to a permit.

It is possible that industrial and other uses for nicotine could arise in relation to which it may be appropriate to provide for importation pursuant to a permit.

It is important to note that a legislative instrument made by the **Secretary** for the purposes of new subregulation 5A(15) would be a disallowable legislative instrument, and therefore subject to parliamentary scrutiny.

Conditions of permissions

New subregulation 5A(16)

New subregulation 5A(16) has the effect that a permission may specify conditions or requirements to be complied with by the holder of the permission (new paragraph 5A(16)(a)), and when the holder must comply with a condition or requirement, whether before or after the importation of the **vaping goods** to which the permission relates (new paragraph 5A(16)(b)).

The purpose of this subregulation is to provide the prescribed authority with discretion to impose conditions on permissions granted to importers for the importation of vaping goods.

This provision will allow conditions and requirements to be imposed, such as testing requirements to confirm compliance with standards and the provision of testing data to the Secretary.

This amendment is consistent with subparagraph 50(3)(b)(ii) of the Customs Act, which provides that, without limiting the generality of paragraph 50(2)(c), the regulations in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the granting of a licence or permission to import goods subject to compliance with conditions or requirements, either before or after the importation of the goods, by the holder of the licence or permission at the time the goods are imported.

New subregulation 5A(17)

New subregulation 5A(17) has the effect that a permission to import a **disposable vape** is, in addition to any condition specified in the permission under new subregulation 5A(16), subject to the condition that the **vape** must be used only for the purposes of supply or use in medical or scientific research.

The purpose of this provision is to ensure that **disposable vapes** are not made available for general supply in the community. **Disposable vapes** are preferred by children and adolescents due to their low cost and ease of concealment from parents and teachers, and are damaging to the environment. It is therefore important that their uses be limited to medical or scientific research.

Revocation of permissions

New subregulation 5A(18)

New subregulation 5A(18) provides that, if a licence to import **vaping goods** specifies a condition or requirement to be complied with by the holder of the permission (new paragraph 5A(18)(a)), and the holder of the permission fails to comply with the condition or requirement (new paragraph 5A(18)(b)), the **Secretary** or an **authorised officer** may revoke the permission, whether or not the holder of the permission is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

New subregulation 5A(18) deals with the circumstances in which the **Secretary** or an **authorised officer** may revoke the permission to import **vaping goods**, whether or not the holder of the permission is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

New subregulation 5A(18) is authority for revocation of permission to import **vaping goods** if a permission to import **vaping goods** specifies a condition or requirement to be complied with by the holder of the permission (new paragraph 5A(18)(a)) and the holder of the permission fails to comply with the condition or requirement in new paragraph 5A(18)(b).

The purpose of this amendment is to allow a revocation of a permission where it is no longer considered to be in the public interest that the goods the subject of the permit should be imported.

Under the provisions of the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002* under which these goods will be permitted for supply in Australia, the **Secretary** can make a determination, which will be published on the **Department's** website, that the supply of the goods be stopped or should cease because:

- the **Secretary** is satisfied that the supply compromises public health and safety; or
- the **Secretary** is satisfied that the goods do not conform with a standard applicable to the goods.

This provision provides authority for a permission to be revoked if such a determination was made.

In those circumstances, the **Secretary** or an **authorised officer** may, in writing, revoke the permission, irrespective of whether or not the holder of the permission is charged with an offence against subsection 50(4) of the Customs Act in respect of the failure to comply with the condition or requirement.

This amendment is consistent with subparagraph 50(3)(b)(iv) of the Customs Act, which provides that, without limiting the generality of paragraph 50(2)(c), the regulations in relation to licences or permissions granted as prescribed by regulations made under this Act—may make provision for and in relation to the revocation of a licence or permission that is granted subject to a condition or requirement to be complied with by a person for a failure by the person to comply with the condition or requirement, whether or not the person is charged with an offence against subsection 50(4) in respect of the failure.

Definitions

New subregulation 5A(19)

New subregulation 5A(19) would introduce a number of new definitions for new regulation 5A.

ABN

The term **ABN** is defined to have the meaning given by section 41 of the *A New Tax System (Australian Business Number) Act 1999*, which defines the term **ABN** (Australian Business Number) for an entity to mean the entity's **ABN** as shown in the Australian Business Register.

Authorised officer

The term **authorised officer** is defined to mean an officer of the **Department** authorised by the **Secretary** under new subregulation 5A(21) to be an **authorised officer**.

Authorised person

The term **authorised person** is defined to mean a person authorised by the **Secretary** under new subregulation 5A(22) to be an **authorised person** for the purposes of this regulation.

Department

The term **Department** is defined to mean the **Department** administered by the Minister administering the *Therapeutic Goods Act 1989*. At the time this explanatory memorandum was prepared, that was the Department of Health and Aged Care.

Disposable vape

The term **disposable vape** is defined to mean a **vape** that:

- is of the kind referred to in paragraph (a) of the definition of **vape** in this regulation (new paragraph (a)); and
- is fully assembled with all the constituent components fixed permanently in place and that is not designed or intended to be disassembled (new paragraph (b)); and
- is pre-filled with a **vape substance** (new subparagraph (c)(i)), or is designed or intended to be supplied pre-filled with a **vape substance** (new subparagraph (c)(ii)); and
- is not designed or intended to be refilled (new paragraph (d)).

A **disposable vape** is a closed system in which the **vape** is pre-filled with **vaping substance** and which is not intended to be reusable or refillable, and is therefore disposed of once the **vaping substance** runs out.

Disposable vapes are distinguishable from reusable vapes which are devices that can be refilled and reused multiple times. The **vape substances** in a **disposable vape** may be liquids or solids and may be contained in pods, capsules or cartridges that are fixed permanently in place and cannot be disassembled or refilled.

Minister

The term **Minister** is defined to mean the Minister administering the *Therapeutic Goods Act 1989*.

Prescribed authority

The term **prescribed authority** is defined to mean any of the following: the **Secretary** (new paragraph (a)), an **authorised officer** (new paragraph (b)), or an **authorised person** (new paragraph (c)).

Registered for GST

The term **registered for GST** is defined to mean registered under the GST Act.

Secretary

The term **Secretary** is defined to mean the **Secretary** of the **Department**, which as indicated by the definition of **Department** introduced above, means the **Department** administered by the Minister administering the *Therapeutic Goods Act 1989*.

Vape

The term **vape** is defined to mean any of the following:

- a device (whether or not filled with a **vape substance**) that generates or releases, or is designed or intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user (new paragraph (a)); or
- a device to which new paragraph (a) would apply were the device not incomplete, damaged, temporarily or permanently inoperable, or unfinished (new paragraph (b)); or
- a device the presentation of which includes an express or implied representation that the device is a device of the kind referred to in paragraph (a) or (b) (new paragraph (c)).

The term **vape** is followed by two notes. Note 1 would remind the reader that examples of devices that are not **vapes** include the following: humidifiers, diffusers, nebulisers and inhalers. Note 2 would remind the reader that this definition is affected by new subregulation 5A(20).

As indicated by the definitions above, **vapes** have two configurations, reusable **vapes**, and **disposable vapes**.

Devices that release vapour or mist into the air, including devices such as humidifiers, diffusers and some steam inhalers, do not meet the definition of a vape because the vapour or mist is not for direct inhalation by the user. Devices that release vapour, aerosol or mist into the air, and direct that air towards the user through a mask, such as some inhalers and nebulisers do not meet the definition of a vape. Devices that do not produce vapour or mist using a heating element, such as nebulisers and most inhalers, do not meet the definition of a vape because they do not generate the vapour or mist using a heating element.

A heat not burn device, which heats processed tobacco without combustion and produces a vapour for direct inhalation, meets the definition of a vape. An e-hookah device that

vaporises **vape substances** for direct inhalation will meet the definition of a **vape**, but a traditional non-electronic shisha device will not be a vape because it does not use electronic means.

It should be noted that the words ‘incomplete, damaged, temporarily or permanently inoperable, or unfinished’ in paragraph (b) refer to goods that are not yet in full working order, but which could be converted to full working order with some additional parts or by assembly of the parts.

New paragraph (c) of this definition would include a vape in relation to which the name, labelling, packaging, or any advertising or informational material associated with its importation, includes an express or implied representation that it is to be used as a **vape**. One example where this may arise would include a device that is included in the same package with a **vape substance** and/or **vape accessories**, making it apparent that it is intended to be used as a **vape**.

Vape accessory

The term **vape accessory** is defined to mean:

- a cartridge, capsule, pod, vial, dropper bottle, drip bottle or other vessel (new paragraph (a)):
 - that contains, or that is designed or intended to contain, a **vape substance**; (new subparagraph (a)(i)); and
 - whether or not integrated with other components of a **vape** (new subparagraph (a)(ii)); or
- a vessel the presentation of which includes an express or implied representation that the vessel is a vessel of the kind referred to in new paragraph (a) (new paragraph (b)).

New paragraph (b) of this definition would include a vape accessory that, from its name and/or packaging, is apparent that it is intended to contain a vape substance, or is included in the same package with a **vape**, making it apparent that it is intended to be used with a **vape** and therefore to contain a **vape substance**.

The note at the end of the term **vape accessory** would remind the reader that this definition is affected by new subregulation 5A(20).

Vape substance

The term **vape substance** is defined to mean:

- a liquid or other substance designed or intended for use in a **vape** (new paragraph (a)); or
- nicotine in solution in any concentration, including in salt or base form (new paragraph (b)); or
- a substance the presentation of which includes an express or implied representation that the substance is a substance of the kind referred to in new paragraph (a) (new paragraph (c)).

The substances referred to in new paragraph (a) of this definition include, but are not limited to, a liquid, gel, solid or salt that is intended for use in a reusable or disposable **vape**. This also applies to bulk **vape substances**, regardless of the quantity, as well as substances

intended for use in a **vape** that are contained in capsules, cartridges, pods, bottles or other containers.

It should be noted that there is no unique chemical or substance that is used only in vaping liquids, gels, solids. Vaping substances can vary greatly in their component ingredients, and include ingredients that are dangerous chemicals in their own right, as well as ingredients that have a significant range of ‘ordinary’ uses such as in the manufacture of cosmetics, pharmaceuticals, foods and industrial goods (for example, glycerine, propylene glycol, essential oils and vitamins). These ingredients that are in widespread use in the community for ordinary purposes will not be affected by this control.

Finished goods that contain nicotine as an ingredient and that are not intended or designed to be used with a vape, such as nicotine patches and nicotine gum, do not meet the definition of a **vaping substance** because they are not nicotine in solution. However, nicotine in solution, including as a raw material or finished good, will meet the definition of a **vape substance** even if the solution is not intended for use with a vape. All liquids designed or intended for use with a **vape** that contain nicotine (as well as liquids designed or intended for use with a **vape** that do not contain nicotine in solution), will meet the definition of a **vape substance**.

Substances made from dried plants, including but not limited to heatsticks made of tobacco intended for use in a heat not burn device, meet the definition in new paragraph (a) as a substance for use in a **vape**.

Substances for use with e-hookah devices will meet the definition of **vape substance**, but shisha tobacco is not generally considered to be for use with an electronic shisha device and therefore will not ordinarily meet the definition of a **vape substance**.

New paragraph (b) of this definition would refer to any concentration of nicotine in solution, including trace elements in highly diluted amounts. Nicotine in solution would meet the definition of new paragraph (b) even if it was not designed or intended to be used to manufacture a liquid or other substance designed or intended for use in a **vape**. Due to its toxicity and potential diversion for use in the manufacture of harmful goods such as recreational vape substances, it is considered appropriate that nicotine in solution be regulated irrespective of its purpose.

New paragraph (c) of this definition would include a substance in relation to which the name, labelling, packaging or any advertising or informational material associated with its importation, includes an express or implied representation that it is to be used in a **vape**. For example, where a substance is labelled as an ‘e-juice’ or an ‘e-liquid’ it will be apparent that it is designed or intended for use with a **vape** and is therefore a **vape substance**, and where a substance is included in the same package with a **vape** and/or **vape accessories**, it may be apparent that it is intended to be used in a **vape**.

The note at the end of the term **vape substance** would remind the reader that this definition is affected by new subregulation 5A(20).

Vaping goods

The term **vaping goods** is defined to mean a **vape**, or a **vape accessory** or a **vape substance**. These terms are defined elsewhere in new subregulation 5A(19). This definition is followed

by a note that reminds the reader that a good may be covered by more than one paragraph of the definition.

For example, a **disposable vape** is covered by both a **vape** and **vape substance**, because a **disposable vape** is a ready-to-use **vape** that contains a **vape substance**, and **vape** can include a part of a device that would be a **vape** if it were not incomplete.

A filled vape cartridge that incorporates a heating element but is not attached to a battery and is not capable of use as a **vape** in its present form would meet the definition of a **vape** because it is an incomplete, unfinished or temporarily inoperable device. It is also a **vape accessory** because it is a cartridge, and it includes a **vape substance** because it is filled with a substance intended for use in a **vape**.

New subregulation 5A(20)

New subregulation 5A(20) provides that, for the purposes of paragraph (c) of the definition of **vape**, paragraph (b) of the definition of **vape accessory**, and paragraph (c) of the definition of **vape substance**, in subregulation 5A(19):

- the presentation of a device, vessel or substance includes matters in relation to:
 - the name of the device, vessel or substance (new subparagraph 5A(20)(a)(i)); and
 - the labelling and packaging of the device, vessel or substance (new subparagraph 5A(20)(a)(ii)); and
 - any advertising or informational material associated with the importation of the device, vessel or substance (new subparagraph 5A(20)(a)(iii)); and
- a device, vessel or substance may be presented as being a kind of device, vessel or substance even if the presentation is capable of being misleading or confusing as to the content or proper use or identification of the device, vessel or substance (new subparagraph 5A(20)(b)(i)), or suggests that the device, vessel or substance has ingredients, components or characteristics that it does not have (new subparagraph 5A(20)(b)(ii)).

New subregulation 5A(20) will allow the enforcement of the ban on vapes even if the products make inaccurate claims or use misleading marketing, and will prevent importers from evading the controls by:

- tweaking the components or ingredients of vaping goods; or
- designing the vaping goods to make them difficult to identify or detect; or
- describing the goods in a way that conceals their purpose to an uninformed observer but signals the intended use to the user.

Marketing can make individuals believe these products are safe for human consumption when they are not. Vaping goods are frequently designed to look like other ubiquitous objects such as pens, USB devices, toys, lip glosses and sippy cups, reinforcing the idea that vaping goods are safe for children when this is not the case. For adults using vaping goods for smoking cessation or recreation the variability in concentration of the ingredients and potential toxicity of the goods increases the risk of harm, particularly when the label is misleading.

The effect of new subregulation 5A(20) is that there is no requirement for testing or identification by an expert on vaping goods before seizure of the goods. In determining if the goods are vaping goods, officers of Customs may consider express and implied terms

associated with name, labelling, packaging and any advertising or informational material associated with the importation of the vaping goods.

Examples of terms that are explicit reference to vaping goods include: vapes, e-cigarettes, e-cigs, e-smoke, e-pens, e-sticks, vape pens, vape sticks, pv (personal vaporiser), ENDS (electronic nicotine delivery system), doubler, shortfills, e-liquid and e-juice. Nicotine and derivatives of the word nicotine, such as nic, and reference to the type of nicotine such as salt or freebase are also explicitly used to refer to vaping products.

Examples of terms that may, in particular contexts, imply that a good is for vaping include tanks, pods, capsules, cartridges, doubler, shortfills, flavour or cloud.

Some vapes are designed with colours and cartoons to be attractive to children and do not contain term related to vaping. Many vapes aimed at adults will have no terms on the label or packaging that uses terms that explicitly related to vaping and associated informational material and advertising may be explicitly designed to avoid using terms related to vaping.

For example, a device called a portable aromatherapy diffuser with promotional material showing young adults using a pen like device held near the face but not in the mouth. The advertising material does not refer to ‘puffs’ but to ‘breaths’ and does not refer to e-liquid but to ‘essential oils’. These implied representations in the advertising material associated with the importation of the device are sufficient for it to be taken to be a *vape*, and therefore it is controlled.

New subregulation 5A(21)

New subregulation 5A(21) provides the statutory power for the **Secretary** to authorise APS employees of the Department of Health and Aged Care, by writing, to be an **authorised officer** for the purposes of administering new regulation 5A.

This authorisation is necessary to ensure the permit regime does not hamper the legitimate trade in smoking cessation products and therapeutic devices used to inhale medicinal substances. It is appropriate for the **Secretary** to be able to authorise an APS employee in the **Department** of Health and Aged Care as an **authorised officer** due to their technical expertise used to currently decide applications for drugs under regulation 5 of the Prohibited Imports Regulations and due to the large volume of permissions that may need to be dealt with under the Regulations.

As **vaping goods** continue to be regulated under new regulation 5A, the effect of this provision is to support consistency in the administration of the permission schemes of **vapes** and **vape substances** across regulation 5 of the Prohibited Imports Regulations and new regulation 5A respectively. Decisions in relation to granting, revoking or refusing a permission are anticipated to need to be made on a regular basis. Delegation to an APS level employee is necessary to ensure applications can be assessed in a timely manner. These employees are already experienced in issuing such permissions and this would ensure that the permissions are administered consistently.

This level of authorisation is consistent with other permission administrative functions under the Prohibited Imports Regulations, including for more sensitive goods such as nicotine and cannabinoids. The Department of Health and Aged Care will ensure that all officers

authorised to hold or perform the duties of an **authorised officer** are suitably qualified and experienced staff within the Regulatory Services and Drug Control Branch.

Officers of the Department of Health and Aged Care authorised as **authorised officers** for the purpose of the definition in new subregulation 5A(21) are APS employees at the Executive Level 1 (EL1) and above within the Office of Drug Control. Authorising EL1 officers and above for the purpose of administering the permission scheme under new regulation 5A is consistent with existing authorisations for the importation of prohibited drugs under regulation 5 of the Prohibited Imports Regulations.

It was not considered appropriate to only authorise officers at the Senior Executive Service (SES) or equivalent level as the limited number and availability of SES employees would impact resourcing and the **Department's** ability to consider applications in a timely manner. This in turn could be of detriment to an applicant's business. Authorising EL1 officers and above serves to ensure a sufficient number of suitably experienced APS employees with the appropriate technical expertise are available to consider the volume of applications that are anticipated to be received.

It is important to note that in practice import permissions will generally be granted by **authorised officers** at the Executive Level 1 (EL1), with EL2 officers granting permissions when there are a large volume of applications for permission to import to be processed.

New subregulation 5A(22)

New subregulation 5A(22) provides that for the purposes of the definition of **authorised person** in new subregulation 5A(19), the **Secretary** may, in writing, authorise the Administrator of an external Territory to be an **authorised person** for the purposes of this regulation.

Administrators of External Territories are appointed by the Governor-General, and are the most senior Australian Government representatives in those territories, exercising all powers, and performing all functions, that are conferred on him or her by or under a law in force in the Territory in accordance with such written directions as are given to him or her by the responsible Commonwealth Minister under this subsection.

In recognition of the role of the Administrator of External Territories, the amendment has the effect that the Administrator could be conferred powers and functions to consider, grant or refuse applications for permission to import **vaping goods**.

Item 2 Subregulation 5HA(1) (after paragraph (a) of the definition of *Initial decision*)

This item of the Amendment Regulations inserts new paragraph (aaa) into the definitions of **Initial decision**, and would have the effect that the term also means a decision, under new subregulation 5A(1), (9), (11), (16) or (18), of a **prescribed authority** (defined in item [1] of the Regulations, above, to mean the **Secretary**, an **authorised officer** or an **authorised person** as the case may be).

Initial decisions made by a **prescribed authority** in relation to an application for permission to import **vaping goods** may be subject to internal review under subregulation 5HA(1) of the Prohibited Import Regulations, and subsequent merits review of a decision may be sought in the Administrative Appeals Tribunal on reconsideration.

The purpose of this amendment is to allow a person whose interests are affected by a decision under new subregulations 5A(1), (9), (11), (16) or (18), to request the *Minister* administering the Therapeutic Goods Act to reconsider the decision.

The *Minister* must reconsider the decision as soon as practicable after receiving this request and may confirm the initial decision, revoke the initial decision or make a decision in substitution for that decision. Under subregulation 5A(8) of the Prohibited Imports Regulations, an application may be made to the Administrative Appeals Tribunal for review of the *Minister's* decision.

Item 3 In the appropriate position before Schedule 1

This item of the Amendment Regulations inserts new regulation 18 to deal with transitional matters arising from the amendments made by this instrument.

New paragraph 18(1)(a) provides that new subregulation 5A(1) as inserted by Schedule 1 to the Amendment Regulations applies in relation to *disposable vapes* imported into Australia on or after 1 January 2024.

New paragraph 18(1)(b) provides that new subregulation 5A(1) as inserted by Schedule 1 to the Amendment Regulations applies in relation to any other *vaping goods* imported into Australia on or after 1 March 2024.

Customs Regulation 2015

The purpose of the amendment to the Customs Regulation is to introduce a new provision that would prescribe *vaping goods* for the purposes of section 209M of the Customs Act, and to permit the surrender of these goods to an officer in a place used by officers for questioning passengers or crew disembarking from a ship or aircraft, as described in section 234AA of the Customs Act.

Item 4 After regulation 119

This item of the Amendment Regulations inserts a new regulation 119A to deal with the surrender of prescribed prohibited imports. New regulation 119A provides that, for the purposes of section 209M of the Customs Act, goods that are prohibited imports of a kind to which regulation 5A of the Prohibited Imports Regulations applies are prescribed.

The effect of this item is that an officer, who is questioning passengers or crew disembarking from a ship or aircraft, has the discretion to request the surrender of *vaping goods* which are prohibited imports by new regulation 5A of the Prohibited Imports Regulations, introduced by item 1 of the Regulations, above.

Statement of Compatibility with Human Rights

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

Customs Legislation Amendment (Vaping Goods) Regulations 2023

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 Disallowable Legislative Instrument

The purpose of the *Customs (Prohibited Imports) Amendment (Vaping goods) Regulations 2023* (Disallowable Legislative Instrument) is to amend the *Customs (Prohibited Imports) Regulations 1956* (Prohibited Imports Regulations) to implement a general prohibition on the importation of vapes, vaping accessories and vape substances (collectively referred to as ‘vaping goods’). The Disallowable Legislative Instrument also amends the *Customs Regulation 2015* (Customs Regulation) to prescribe vaping goods for the purposes of section 209M of the *Customs Act 1901* (Customs Act), and to permit the surrender of these goods to an officer in a place used by officers for questioning passengers or crew disembarking from a ship or aircraft, as described in section 234AA of the Customs Act.

The Australian Border Force enforces import control under the Prohibited Imports Regulations over goods that arrive at the border. These controls are in place to ensure that imported goods do not pose a threat to the wider community. The use of vapes and vape substances are rapidly increasing. Many such products contain nicotine, which is highly addictive and poses serious health risks, and medical experts have serious concerns about the health effects of other harmful substances in vaping substances.

The dramatic increase in vaping recent years poses a major risk to population health and threatens to disrupt the significant achievements that Australia has made in tobacco control to date. Research suggests that vaping is a gateway to smoking.

Vaping mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely. Never-smokers who vape are approximately three times more likely to take up cigarette smoking than those who do not vape. Further, there is substantial evidence that vaping results in dependence, and causes respiratory disease, severe burns, nicotine poisoning and seizures. The long-term health effects of vaping are not known.

The amendments contained in the Disallowable Legislative Instrument address the risks posed by vaping to children and young people in Australia, while preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine addiction.

This Disallowable Legislative Instrument inserts new regulation 5A into the Prohibited Imports Regulations, which restricts the lawful importation of vapes to those that are included in the Australian Register of Therapeutic Goods; those for which the importer has notified the Secretary of the Department of Health and Aged Care that the vape is compliant with relevant

quality standards; and vapes that are only for medical or scientific research. Importers are required to obtain a licence and permit to import such products under new regulation 5A.

The Disallowable Legislative Instrument also introduce an authority for the Minister administering the *Therapeutic Goods Act 1989* to approve the importation of other vaping goods in a legislative instrument if the goods meet one or more of the criteria specified in new regulation 5A, and authorises for the Secretary to specify, by legislative instrument, purposes for which vaping goods may be imported and kinds of vaping goods that may be imported..

Under the new regulation 5A, the Secretary of the Department of Health, or an officer or a person authorised by the Secretary, may grant a licence and permission to enable the import of vaping goods. Applicants for permission can be either a person or entity who will be in effect a supplier of goods that meets requirements set out in the *Therapeutic Goods Act 1989* (Therapeutic Goods Act), or a person or entity that conducts medical or scientific research. To ensure that therapeutic uses may continue, new regulation 5A also provides exemptions from the prohibition through a mechanism for the approval of vaping goods.

A prescribed authority's power to grant a licence to import vaping goods can only be granted to an applicant who has provided all reasonably required information to establish they are suitable to hold a license and who is intending to manufacture or supply vaping goods as part of the applicant's business, or use them or medical or scientific research. Further the applicant must have an ABN and be registered for GST and hold any licence or other approval required in the State or Territory they conduct their business. This mirrors the administrative arrangements for applications for licences to import drugs under regulation 5 of the Prohibited Imports Regulations, to ensure consistency and expediency in the regulatory administration of the importation of vaping goods under new regulation 5A.

The possibility of applying for and being granted permission is not available for importation through the post, which is prohibited. Importing a prohibited import, such as vaping goods, without permission, is a strict liability offence pursuant to section 233 of the Customs Act. Further, importing vaping goods in contravention of a condition imposed on a licence or permission is also a strict liability offence pursuant to section 50 of the Customs Act.

However, some exemptions from the general prohibition on the importation of vaping goods apply in specific circumstances.

A person who is a passenger on board a ship or aircraft (or the carer for one or more such passengers) may import no more than two vapes and a limited quantity of vaping substances for use in connection of the treatment of the person or of another passenger under the care of the person.

New regulation 5A does not prevent persons having access to vapes and vaping substances from a licenced and permitted importer provided they have a relevant authority of a medical practitioner.

By prescribing vaping goods for the purposes of section 209M of the Customs Act, the related amendment contained in the Disallowable Legislative Instrument allows an officer of Customs who is questioning passengers or crew disembarking from a ship or aircraft the discretion to request the surrender of vaping goods instead of seizing the goods. This has the

effect of the goods being immediately forfeited to the Crown and the importer cannot be prosecuted for an offence if importing a prohibited import.

Human rights implications

This Disallowable Legislative Instrument engages the following rights:

- the right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR);
- the obligation to take measures to ensure the survival and development of children Article 6(2) of the *Convention on the Rights of the Child* (CRC);
- the obligation to take appropriate measures to protect children from the illicit use of narcotic drugs and psychotropic substances in Article 33 of the CRC;
- the right to presumption of innocence in Article 14(2) of the *International Covenant on Civil and Political Rights* (ICCPR); and
- the right to privacy in Article 17 of the ICCPR.

Right to health

Article 12 of the ICESCR protects a person's right to the highest standards of physical and mental health. Under Article 12(2)(c), the right to health includes the obligation on the State to take steps to prevent, treat and control diseases.

This Disallowable Legislative Instrument promotes the right to health by supporting policy initiatives aimed at reducing the risk to public health caused by vaping. It does this by restricting access to vaping goods, thus limiting the potential for people to become addicted to vaping, or to transfer to cigarettes and become addicted to smoking, and by limiting the risk of poisoning from ingestion of vaping substances.

Measures to ensure the survival and development of children

Article 6(2) of the CRC requires state parties to take measures to ensure the survival and development of children to the greatest extent possible.

Vaping goods pose a particular risk to children. The variability in concentration and toxicity of the active ingredients, such as nicotine, in vaping goods increases the risk that children who consume nicotine may ingest a fatal dose or suffer severe adverse effects. Vaping goods are frequently designed to look like other ubiquitous objects such as pens, USB devices, lip gloss, toys and sippy cups. The designs use colours, illustrations and cartoons attractive to children reinforcing the idea that vaping goods are safe for children when this is not the case.

This Disallowable Legislative Instrument promotes measures to ensure the survival and development of children by supporting policy initiatives aimed at reducing the risk to children's health posed by vaping. It does this by restricting access to vaping goods, thus limiting the potential for children's health and development to be adversely affected by vaping and vaping substances.

Right to presumption of innocence

Article 14(2) of the ICCPR protects the rights of every person charged with a criminal offence to be presumed innocent until proven guilty according to law.

The presumption of innocence imposes on the prosecution the burden of proving the charge and guarantees that no guilt can be presumed until the charge has been proved beyond reasonable doubt. Consistency with the presumption of innocence requires that the prosecution prove each element of a criminal offence beyond reasonable doubt.

The application of strict liability to an element of an offence may engage and limit the right to be presumed innocent as it allows for the imposition of criminal liability without the need for the prosecution to prove fault.

The import controls inserted by the Disallowable Legislative Instrument mean that importing vaping goods without permission, and importing vaping goods in contravention of a licence or permission condition, are strict liability offences under sections 233 and 50 of the Customs Act respectively. Applying strict liability is appropriate in these circumstances as persons engaged in importing would be expected to be aware of, and comply with, the requirements of the Customs Act. It would not be appropriate for the prosecution to have to demonstrate that a person knew that they had failed to meet those requirements. However, the general defence of mistake of fact would be available to the defendant.

Under international human rights law, a reverse onus provision will not violate the presumption of innocence if the law is reasonable in the circumstances and maintains the rights of the accused. Such a provision may be justified if the nature of the offence makes it very difficult for the prosecution to prove each element, or if it is clearly more practical for the accused to prove a fact than for the prosecution to disprove it. Where a person is suspected to imported vaping goods without permission, or importing vaping goods in contravention of a licence or permission condition, it is more practical for the person to demonstrate that their knowledge of a fact rather than requiring public authorities to identify and gather evidence necessary to prove each element of an offence.

Making the offences strict liability offences also operates to deter behaviour that has the potential to have harmful impacts on public health in Australia.

The strict liability nature of the offences is reasonable, necessary and proportionate to achieving the aim of protecting public health and prohibiting the importation of harmful vaping goods into Australia. For these reasons, the strict liability offences are not inconsistent with the presumption of innocence set out in Article 14(2) of the ICCPR.

Right to Privacy

Article 17(1) of the ICCPR requires that no one be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence.

Interferences with privacy may be permissible where it is authorised by law and is not arbitrary. For an interference with the right to privacy not to be arbitrary, the interference must be for a reason consistent with the provisions, aims and objectives of the ICCPR and be reasonable in the particular circumstances. The United Nations Human Rights Committee has interpreted ‘reasonableness’ in this context to mean that ‘any interference with privacy must be proportional to the end sought and be necessary in the circumstances of any given case’. The term unlawful means that no interference can take place except as authorised under domestic law.

The Disallowable Legislative Instrument engages the right to privacy by enabling the Secretary of the Department of Health or a prescribed authority to require an importer to provide personal information on an application for a license or permission to import vaping goods.

In exercising these powers, the Secretary of the Department of Health or a prescribed authority may seek additional information from importers about all relevant matters including their suitability to hold a license, the nature of their business or medical or scientific research, the security of the premises where the goods are held and the nature of the vaping goods and the intended use of the vaping goods. This could include matters relating to propriety, such as previous criminal convictions.

The Department of Health or a prescribed authority will use this information to determine the applicants suitably to hold a license and a permit and whether the goods meet the requirements of the *Therapeutic Goods Act 1989*.

The Disallowable Legislative Instrument only allows authorities to require personal information relating to an individual's private life to the extent that it is necessary to consider their suitability to obtain and hold a licence, in order to ensure the integrity of the supply of therapeutic vaping goods in Australia.

To the extent the power to collect information under the Disallowable Legislative Instrument may limit the right to privacy under Article 17 of the ICCPR, this limitation is permissible because the collection of personal information would be lawful, would not be arbitrary and would be reasonable, necessary and proportionate to achieving the aim of protecting public health and prohibiting the unregulated importation of harmful vaping goods into Australia. For these reasons, the Disallowable Legislative Instrument is not inconsistent with the right to privacy set out in Article 17(1) of the ICCPR.

Conclusion

The Disallowable Legislative Instrument is compatible with human rights because it promotes human rights. To the extent that the Disallowable Legislative Instrument may limit Articles 14(1) and 17 the ICCPR, the limitations are reasonable, necessary and proportionate.

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