

# **Customs Legislation Amendment (Vaping Goods) Regulations 2023**

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 13 December 2023

David Hurley Governor-General

By His Excellency's Command

Clare O'Neil Minister for Home Affairs



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#### 1 Name

This instrument is the Customs Legislation Amendment (Vaping Goods) Regulations 2023.

#### 2 Commencement

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

Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	At the same time as the <i>Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023</i> commence.	1 January 2024
	However, the provisions do not commence at all if that instrument does not commence.	
Note:	This table relates only to the provisions of this instrument as o not be amended to deal with any later amendments of this instrument.	

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

## 3 Authority

This instrument is made under the Customs Act 1901.

#### 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

# **Schedule 1—Amendments**

# Customs (Prohibited Imports) Regulations 1956

#### 1 After regulation 5

Insert:

## 5A Importation of vaping goods

Prohibition on importation of vaping goods

- (1) Subject to subregulations (2) to (4), the importation into Australia of vaping goods is prohibited unless:
  - (a) the person importing the vaping goods is the holder of:
    - (i) a licence to import the vaping goods granted by a prescribed authority under this regulation; and
    - (ii) a written permission to import the vaping goods granted by a prescribed authority under this regulation; and
  - (b) the permission, or a copy of the permission, is produced to the Collector; and
  - (c) the importation is by means other than post.

Note: A number of expressions used in this regulation are defined in subregulation (19), including the following:

- (a) disposable vape;
- (b) vape;
- (c) vape accessory;
- (d) vape substance;
- (e) vaping goods.
- (2) Subregulation (1) does not apply to the importation of vaping goods by a person (the *first person*) on board a ship or aircraft, if:
  - (a) the vaping goods are presented by the first person as being for use in connection with the treatment of the first person or one or more other persons on board the ship or aircraft who are under the care of the first person; and
  - (b) the vaping goods do not include more than the following for each person referred to in paragraph (a):
    - (i) 2 vapes;
    - (ii) 20 vape accessories that are cartridges, capsules or pods;
    - (iii) 200 ml of vape substances in liquid form.
- (3) Subregulation (1) does not apply to:
  - (a) an importation that meets the requirements of:
    - (i) paragraphs 5(1)(a) to (d); or
    - (ii) paragraph 5(2)(b); or
  - (b) an importation of a disposable vape or a vape accessory containing a substance, if the importation of that substance meets the requirements of:
    - (i) paragraphs 5(1)(a) to (d); or
    - (ii) paragraph 5(2)(b).

- (4) Subregulation (1) does not apply to vaping goods in respect of the importation of which an approval is in force under subregulation (5).
- (5) The Minister may, by legislative instrument, approve the importation into Australia of vaping goods that meet one or more of the following:
  - (a) the vaping goods are specified in, or included in a class of vaping goods specified in, the approval;
  - (b) the vaping goods are imported in a form (including a concentration) specified in the approval;
  - (c) the vaping goods are imported by a person, or class of persons, specified in the approval;
  - (d) the vaping goods do not exceed a value or amount specified in the approval;
  - (e) the vaping goods are imported in a way, or by a means, specified in the approval.

Applications for licences and permissions

- (6) An applicant for a licence or a permission to import vaping goods must:
  - (a) make the application on the form approved by the Secretary; and
  - (b) lodge the application with a prescribed authority; and
  - (c) give to the prescribed authority any information that the prescribed authority reasonably requires for the purpose of making a decision on the application.

Dealing with applications for licences

- (7) A prescribed authority must not grant an applicant a licence to import vaping goods unless:
  - (a) the applicant has given the prescribed authority all the information required by the prescribed authority under paragraph (6)(c); and
  - (b) the prescribed authority is satisfied that the applicant is to import the vaping goods:
    - (i) 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 for medical or scientific research; or
    - (ii) for disposable vapes—only for the purposes of supply or use for medical or scientific research; and
  - (c) the applicant is registered for GST; and
  - (d) the applicant has an ABN; and
  - (e) if the applicant is required, under a law of a State or Territory in which the applicant conducts business, to hold a licence or other approval (however described) in relation to the vaping goods—the applicant holds the relevant licence or approval.
- (8) In considering whether to grant a licence, the prescribed authority may consider any relevant matter.

Conditions of licences

- (9) A licence may specify:
  - (a) conditions or requirements to be complied with by the holder of the licence; and

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

Revocation of licences

- (11) If:
  - (a) a licence to import vaping goods specifies a condition or requirement to be complied with by the holder of the licence; and
  - (b) the holder of the licence fails to comply with the condition or requirement; the Secretary or an authorised officer may, in writing, revoke the licence, whether or not the holder of the licence is charged with an offence against subsection 50(4) of the Act in respect of the failure to comply with the condition or requirement.

Dealing with applications for permissions

- (12) A prescribed authority must not grant an applicant a permission to import vaping goods, unless:
  - (a) the applicant is the holder of a licence granted under subregulation (1) to import the vaping goods; and
  - (b) one or more of the following apply:
    - (i) the vaping goods are included in the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act* 1989:
    - (ii) the vaping goods meet the notification requirements in subregulation (13);
    - (iii) the vaping goods are to be imported only for the purposes of supply or use for medical or scientific research 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;
    - (iv) the vaping goods are to be imported for a purpose specified for the goods by the Secretary under subregulation (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;
    - (v) the vaping goods are vaping goods of a kind specified by the Secretary under subregulation (15).
- (13) For the purposes of subparagraph (12)(b)(ii), vaping goods meet the notification requirements in this subregulation, if:
  - (a) for a vaping good that is a therapeutic cannabis vaping good within the meaning of the *Therapeutic Goods (Medical Devices) Regulations 2002*—a notice, in a form approved by the Secretary, has been given to the Secretary stating that the device:
    - (i) complies with the essential principles (within the meaning of the *Therapeutic Goods Act 1989*); or

- (ii) is imported with the consent of the Secretary under section 41MA or 41MAA of that Act; or
- (b) for any other vaping goods:
  - (i) 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; or
  - (ii) a notice in relation to the vaping goods has been given in accordance with paragraph (a) of the column headed "Conditions" of item 2.18 of Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; or
  - (iii) 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*; or
  - (iv) 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*.
- (14) The Secretary may, by legislative instrument, specify purposes for the purposes of subparagraph (12)(b)(iv). 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*.
- (15) The Secretary may, by legislative instrument, specify kinds of vaping goods for the purposes of subparagraph (12)(b)(v).

Conditions of permissions

- (16) A permission may specify:
  - (a) conditions or requirements to be complied with by the holder of the permission; and
  - (b) 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.
- (17) A permission to import a disposable vape is, in addition to any condition specified in the permission under subregulation (16), subject to the condition that the vape must be used only for the purposes of supply or use for medical or scientific research.

Revocation of permissions

- (18) If:
  - (a) a permission to import vaping goods specifies a condition or requirement to be complied with by the holder of the permission; and
  - (b) the holder of the permission fails to comply with the condition or requirement;

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

#### **Definitions**

#### (19) In this regulation:

**ABN** has the meaning given by section 41 of the A New Tax System (Australian Business Number) Act 1999.

*authorised officer* means an officer of the Department authorised by the Secretary under subregulation (21) to be an authorised officer.

*authorised person* means a person authorised by the Secretary under subregulation (22) to be an authorised person.

**Department** means the Department administered by the Minister administering the *Therapeutic Goods Act 1989*.

#### disposable vape means a vape:

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

*Minister* means the Minister administering the *Therapeutic Goods Act 1989*.

#### prescribed authority means any of the following:

- (a) the Secretary;
- (b) an authorised officer;
- (c) an authorised person.

registered for GST means registered under the GST Act.

**Secretary** means the Secretary of the Department.

#### vape means:

- (a) 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; or
- (b) a device to which paragraph (a) would apply were the device not incomplete, damaged, temporarily or permanently inoperable, or unfinished; or
- (c) 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).

Note 1: Examples of devices that are not vapes include the following:

- (a) humidifiers;
- (b) diffusers;
- (c) nebulisers;
- (d) inhalers.

Note 2: This definition is affected by subregulation (20).

#### vape accessory means:

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

Note: This definition is affected by subregulation (20).

#### vape substance means:

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

Note: This definition is affected by subregulation (20).

#### vaping goods means:

- (a) a vape; or
- (b) a vape accessory; or
- (c) a vape substance.

Note: A good may be covered by more than one paragraph of the definition.

- (20) 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 (19):
  - (a) the presentation of a device, vessel or substance includes matters in relation to:
    - (i) the name of the device, vessel or substance; and
    - (ii) the labelling and packaging of the device, vessel or substance; and
    - (iii) any advertising or informational material associated with the importation of the device, vessel or substance; and
  - (b) a device, vessel or substance may be presented as being a kind of device, vessel or substance even if the presentation:
    - (i) is capable of being misleading or confusing as to the content or proper use or identification of the device, vessel or substance; or
    - (ii) suggests that the device, vessel or substance has ingredients, components or characteristics that it does not have.
- (21) For the purposes of the definition of *authorised officer* in subregulation (19), the Secretary may, in writing, authorise an officer of the Department to be an authorised officer for the purposes of this regulation.
- (22) For the purposes of the definition of *authorised person* in subregulation (19), the Secretary may, in writing, authorise the Administrator of an external Territory to be an authorised person for the purposes of this regulation.

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

Insert:

(aaa) of a prescribed authority under subregulation 5A(1), (9), (11), (16) or (18); or

# 3 In the appropriate position before Schedule 1

Insert:

# 18 Transitional matters—amendments made by the Customs Legislation Amendment (Vaping Goods) Regulations 2023

Subregulation 5A(1) of these Regulations, as inserted by Schedule 1 to the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*, applies in relation to:

- (a) disposable vapes imported into Australia on or after 1 January 2024; and
- (b) any other vaping goods imported into Australia on or after 1 March 2024.

# Customs Regulation 2015

# 4 After regulation 119

Insert:

# 119A Surrender of prescribed prohibited imports

For the purposes of section 209M of the Act, goods that are prohibited imports of a kind to which regulation 5A of the Prohibited Imports Regulations applies are prescribed.