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Committee on Import Licensing

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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES¹

NOTIFICATION UNDER ARTICLE 7.3 OF THE AGREEMENT ON IMPORT LICENSING PROCEDURES (2018)

AUSTRALIA

The following communication, dated 21 August 2019, is being circulated at the request of the delegation of Australia.

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¹ See document G/LIC/3, Annex, for the Questionnaire.

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1 ANIMALS (INCLUDING BIRDS, FISH AND INSECTS) AND ANIMAL PRODUCTS, PLANTS AND GOODS OF GENERAL QUARANTINE CONCERN

Outline of System

1. The Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) regulates international trade in Australian native species, live animals and plants, and species listed under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

EPBC Act - https://www.legislation.gov.au/Details/C2016C00777

EPBC Regulations - https://www.legislation.gov.au/Details/F2016C00914

The *Biosecurity Act 2015* applies controls to the importation of all plants, parts of plants and plant products, all animals (including birds, fish and insects), animal products, soil and other items of general quarantine concern.

Biosecurity legislation: https://www.legislation.gov.au/Details/C2019C00097

Sections of the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) control the importation of some animals and plants.

Information to be found at: <u>https://www.comlaw.gov.au/Details/F2016C00106</u>

Purposes and coverage of licensing

2. Apart from exports, the EPBC Act regulates:

- the import of all live animals and plants;
- the import of non-live animal and plant specimens, including parts and derivatives, of species listed under CITES.

The purpose of Australia's biosecurity legislation is to manage the risk of introduction of pests and disease that could damage plant, animal or human health or the environment. Australia's biosecurity legislation applies to the importation of all plants, animals and their products and derivatives.

The Customs (Prohibited Imports) Regulations 1956 control the importations of: fish caught by foreign-based fishing vessels and Patagonian and Antarctic toothfish. The Regulations also control the import of raw tobacco and certain plant material containing drugs.

3. The EPBC Act and biosecurity legislation apply to the importation of goods from all countries.

4. The EPBC Act seeks to implement Australia's obligations under CITES, by regulating international trade in wildlife and wildlife products, to contribute to the protection and conservation of species that are endangered, or could become endangered, and to facilitate legal, sustainable trade in wildlife. The EPBC Act is not intended to restrict the quantity or value of imports.

The biosecurity legislation is not intended to restrict the quantity or value of imports but to manage the risk of introduction of exotic pests and diseases associated with importation for the purpose of protecting plant, animal and human health and the environment. The legislation also seeks to protect the Australian environment against further establishment of pest species of plants and animals by controlling the importation of certain live plants, animals and other biological material. Live animals and plants may only be imported if the species are included on the *List of Specimens taken to be Suitable for Live Import* under the EPBCAct.

5. The controls on the importation of goods specified in this category are statutory requirements under the legislation detailed below:

- Environment Protection and Biodiversity Conservation Act 1999;
- Environment Protection and Biodiversity Conservation Regulations 2000;
- Biosecurity Act 2015;
- Customs (Prohibited Imports) Regulations 1956.

The Commonwealth Department of the Environment and Energy is responsible for administration of the EPBC Act. The Commonwealth Department of Agriculture is responsible for administration of animal and plant quarantine legislation. The Department of Home Affairs is responsible for administration of the Customs (Prohibited Imports) Regulations 1956.

The legislation does not allow for administrative discretion regarding goods/items subject to import controls. It is not possible for the Government or executive branch to abolish the systems without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Applications should be made well in advance of arrival of the goods to allow time for the application to be assessed against the legislation and the relevant import policy. Under the EPBC Act, once a permit application is received, there is a 40-business day statutory timeframe in which a decision regarding the application must be made. Not all goods require an import permit and clearance to import can be given at the point of entry provided the import conditions have been met. Normally permits, including CITES permits, cannot be issued retrospectively.
- (b) In the case of most importations in this category it will not be possible for permission to be issued immediately on request.
- (c) No, permits may be issued at any period of the year.
- (d) Applications for permission to import most animals, animal products, plants and plant products into Australia involve an approach to a single agency - Department of Agriculture - unless the specimens are listed under CITES or Part 2 of the List of Specimens taken to be Suitable for Live Import (live import list) under the EPBC Act, in which case an import permit from the Department of the Environment and Energy is also required. The importation of some products is, by law, subject to certain quarantine conditions, outlined in the Department of Agriculture Biosecurity Import Conditions database http://www.agriculture.gov.au/import/bicon. If the good to be imported is regulated by more than one agency, import permission is generally required from both agencies before the good may be imported. Live animals and plants must be included on the live import list under the EPBC Act before they may be imported.

8. An application to the Department of Agriculture for an import permit may only be refused under the ordinary criteria for such applications. Reasons for refusal will be advised. There are legislated

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structures in place that allow applicants to request a review of a decision to refuse to grant an import permit.

For permit decisions under the EPBC Act, applicants may appeal on the merits of the decision to the Administrative Appeals Tribunal (AAT). Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

The Biosecurity Act 2015 provides the department with an option to apply a fit and proper person test to import permit applicants and their associates. The test supports the trust placed on importers who are granted import permits. Not all permit applicants will be subject to a fit and proper person test - this test will only be used at the department's discretion.

9. (a) Not applicable.

(b) All Australian persons, firms and institutions are eligible to apply for permission to import.

Documentation and other requirements for application for licence

10. Applications for permission to import must be made electronically for all commodities through the Department of Agriculture BICON system. Conditions for imports into the Australian external territories of Norfolk Island, Christmas Island and the Cocos (Keeling) Islands are not contained in BICON. For information about all imports into these Australian external Territories, please visit http://www.agriculture.gov.au/import/goods/external-territories.

Where the importation of the item comes under the jurisdiction of the Department of the Environment and Energy, applications for permission to import must be made electronically to the Minister for the Environment and Energy. The link to the application form can be found at: <u>https://onlineservices.environment.gov.au/</u>.

Importers should consult the BICON database (<u>http://www.agriculture.gov.au/import/online-services/bicon</u>) to determine if a commodity intended for import to Australia needs an import permit and/or treatment or if there are any other biosecurity prerequisites. Permits must be obtained prior to importation and are required on importation. Applications for permits may be lodged electronically (<u>https://bicon.agriculture.gov.au/BiconWeb4.0</u>). Other documentation required is dependent on the type of commodity and the import conditions of the permit or as listed on the BICON database. For the import of CITES listed specimens, both CITES export and import permits are generally required upon importation. The import of live specimens may also require an import permit.

11. Where the importation of the item comes under the jurisdiction of the Department of the Environment and Energy, an Australian import permit is required unless the specimens are considered to be personal and household effects, or they are pre-CITES <u>and</u> non-live. In most cases of CITES-listed specimens, CITES documentation from the country of export is required. Original documents must travel with the goods.

12. Information on fees and charges for the importation of items that come under the jurisdiction of the Department of Agriculture may be found at: <u>http://www.agriculture.gov.au/fees</u>.

Information regarding fees and charges relating to the application for CITES import permits, and live specimen permits, is available at: <u>http://www.environment.gov.au/biodiversity/wildlife-trade/permits/fees</u>.

13. There is no deposit or advance payment requirement associated with the issue of licenses, although assessment fees apply for most Department of Agriculture permit applications. An application (processing) and assessment fee for a Department of Agriculture permit is charged automatically when a permit application is accepted, regardless of whether or not the permit is issued. Further, the Department of the Environment and Energy also charges an application fee at the time of application. The fee is not refundable, regardless of whether or not a permit is issued and/or used.

Conditions of licensing

14. The period of validity of a permit depends on the nature of the importation: specific details to be supplied on enquiry. Legislation will normally not allow for continuing permission. Individual assessments of permit applications will determine the appropriate validity period, which is generally one or two years for Department of Agriculture permits. From time to time, a permit will be issued with a different validity, such as short-term importation of artefacts for a museum exhibition. CITES permits issued by the Department of the Environment and Energy are valid for up to six months. The period of validity cannot be extended.

15. There is no penalty for the non-utilisation of a permit or a portion of a permit.

16. Biosecurity import permits are not transferrable between importers. Permits issued under the EPBC Act may be transferred under very limited circumstances.

17. Biosecurity import permits often have end use restrictions placed on the goods (e.g. for human consumption only) and/or types of treatments they have to undergo prior to or after the goods arrive in Australia (e.g. product has been heat treated at 100 degree Celsius for 30 minutes).

- (a) Not applicable.
- (b) Conditions may be applied in respect of such issues as custody, end use, disposal or distribution of imported goods as well as pre-export treatment, testing, certification or on-arrival treatment or quarantine.

Other procedural requirements

18. No.

19. Not applicable.

2 ANZAC GOODS

Outline of System

1. There are two regulations under which the word "Anzac" is protected in Australia – Protection of Word "Anzac" Regulations (Anzac Regulations) and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations).

Importation into Australia of goods the description of which includes or bears the word "Anzac", or advertising matter relating to those goods, is controlled by the PI Regulations and is prohibited except with the written permission of the Minister for Veterans' Affairs (the Minister) or an authorised officer.

It is highly likely that a person making an application to import "Anzac" goods under the PI Regulations will also need to apply to use the word "Anzac" under the Anzac Regulations.

Purposes and coverage of licensing

2. Licensing system maintained and products covered include: the Anzac Regulations and the PI Regulations.

The Anzac Regulations prevent the use of the word "Anzac" without the written permission of the Minister for Veterans' Affairs.

The purpose of Regulation 4V of the PI Regulations is to prohibit the importation of all goods into Australia that include or bear the word "Anzac", unless: the person importing the goods is the holder of a written permit granted by the Minister for Veterans' Affairs or an authorised officer; and the permit is produced at or before the time of importation. The Minister or an authorised officer may specify conditions or requirements to be complied with by the holder of the permission or permit to import "Anzac" goods, and may, for any such condition or requirement, specify a time period before the permission expires. The Minister or an authorised officer may revoke permission where the conditions of the permit are not met.

In certain circumstances, providing the goods obtain approval status, importers are able to obtain retrospective import approval after the goods have arrived in Australia. However, if the "Anzac" goods in question do not receive ministerial approval they may be seized or retained by the Australian Border Force (ABF).

3. The regulation applies to the importation of goods from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports. The PI Regulations, in conjunction with the Anzac Regulations, seek to protect the inappropriate use and commercial exploitation of the word "Anzac" and to protect the significance of the word.

5. The controls on the importation of "Anzac" goods are statutory requirements and cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) An application for the importation of "Anzac" goods into Australia should be made well in advance of the arrival of the goods. Permit applications may take between six to twelve weeks to process because of the checks made on the individual or company applying to import the "Anzac" goods. Checks are also undertaken on the nature of the goods and their intended use.

The importation of "Anzac" goods is prohibited without written approval from the Minister for Veterans' Affairs. Goods that arrive into port without approval will be seized by the Australian Border Force.

In addition to the PI Regulations, the Anzac Regulations prohibit the use of the word "Anzac" or any word resembling the word "Anzac" in connection with any trade, business, calling, or profession without the Minister or an authorised officer's written approval. Persons applying to import "Anzac" goods may also require written consent to use the said "Anzac" goods under the Anzac Regulations.

- (b) A permit cannot be granted immediately on request as certain conditions must be fulfilled. Processing and assessing applications includes extensive checks and the preparation of a brief for the Minister's consideration and decision.
- (c) Applications can be made at any time of the year.
- (d) The Department of Veterans' Affairs issues permits for the importation of "Anzac" goods in accordance with Regulation 4V of the PI Regulations, and Permission to Use Word "Anzac" in accordance with the Anzac Regulations. When considering permit applications, other authorities may be contacted by the Department to verify application details.

8. An application for a permit may be refused if: the Minister considers that approving the application would cause offence; use of the word "Anzac" on the imported goods is inappropriate; the application does not fall within the intent of the Regulations, e.g. the use of the word "Anzac" on an inappropriate product; the applicant is not considered fit and proper; or further permission is required, but has not been obtained. A permit may be revoked if the applicant fails to comply with the conditions of the permit.

An unsuccessful applicant is advised in writing of the Minister for Veterans' Affairs' decision and the reason for it. There are no appeal provisions under the Regulations; however, the Minister will consider a request for reconsideration if the applicant is able to provide new information in support of their application. In addition, an appeal may be made on the decision-making process itself under the Administrative Decisions (Judicial Review) Act 1977.

Eligibility of importers to apply for licence

- 9. (a) Any person, firm or institution is eligible to apply to the Minister for Veterans' Affairs to import "Anzac" goods.
- (b) Not applicable.

Documentation and other requirements for application for licence

10. An application can be submitted in the form of a letter or e-mail. There is no specific format. Every application is considered on its individual merits and if additional information is required the applicant will be contacted.

Applications should include, but are not restricted to:

- name of the applicant/importer (person and organisation);
- name and address of registered company/premises;
- nature of the business and purpose of the proposed "Anzac" goods;
- a current copy of the company Australian Business Number (ABN) or Australian Company Number (ACN) registration;
- product description, full colour copy of item and text;
- letters of support from the ex-service community;
- proposed date of import;
- the duration permit is required; and
- where applicable, the name of the end user and the use of the end goods.

11. A copy of the signed permit is required at the time of importation.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. The period of the import permit is specified in the permit issued to the applicant and is based on the requirements of each application. Unless otherwise noted, an import permit is usually required for every delivery.

The period of an existing permit cannot be extended, but a new permit may be issued upon request to the Minister.

- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Permits/licences are not transferable between importers.

17. (a) Not applicable.

(b) Not applicable.

Other procedural requirements

18. No.

19. Not applicable.

3 ASBESTOS

The importation of asbestos into Australia is controlled under the *Customs (Prohibited Imports) Regulations 1956* (PI Regulations).

Asbestos means the asbestiform varieties of mineral silicates belonging to the serpentine or amphibole groups of rock forming minerals including the following:

- (a) actinolite asbestos;
- (b) grunerite (or amosite) asbestos (brown);
- (c) anthophyllite asbestos;
- (d) chrysotile asbestos (white);
- (e) crocidolite asbestos (blue);
- (f) tremolite asbestos;
- (g) a mixture that contains one or more of the minerals referred to in paragraphs (a) to (f).

Please also refer to the section on *Industrial Chemicals*, including details of the Rotterdam convention, as it applies to actinolite; amosite; anthophyllite; crocidolite and tremolite asbestos.

Outline of System

1. Under the PI Regulations, the importation of asbestos, or goods containing asbestos, is subject to prohibition. The regulations empower the Minister (the WHS Minister) administering the Work Health and Safety Act 2011 (WHS Act) to grant permission to import asbestos in certain circumstances.

Purposes and coverage of licensing

2. Under the PI Regulations, the importation of asbestos, or goods containing asbestos, is prohibited unless:

- (a) The asbestos or goods containing asbestos are hazardous waste as defined in Section 4 of the Hazardous Waste (Regulation of Exports and Imports) Act 1989 (HW Act). Goods of this type must be imported in accordance with the provisions of the HW Act;
- (b) The goods are raw materials containing naturally occurring traces of asbestos; or
- (c) Permission has been granted by the WHS Minister for one or more of the following purposes:
 i) in any case: research, analysis or display;
 - ii) if the importation is from and Australian external Territory: disposal in a mainland State or Territory; or
- (d) A confirmation from an authority of an Australian State or Territory is in force stating that the proposed use of the asbestos or goods is research, analysis or display in accordance with WHS laws of that State or Territory; or
- (e) The importation is of a ship or resources installation and all of the following apply:
 - i) of at least 150 gross tonnage as shown on the International Tonnage Certificate;
 - ii) the asbestos was installed or affixed before 1 January 2005;
 - iii) the asbestos in the ship or resources installation will not be a risk to any person unless it is disturbed.
- 3. The regulations apply to the importation of goods from all countries.

4. The importation of all forms of asbestos is regulated as a community and workplace safety measure. The importation of asbestos is subject to prohibition to reduce and prevent occupational and environmental exposures to asbestos fibres, and the possible adverse health outcomes attributed to these exposures. In addition to the prohibition of the importation of asbestos, the use of asbestos is prohibited in all Australian state, territory and Commonwealth work health and safety regulations. The import prohibition applies to all goods that contain asbestos regardless of their value.

5. The control on importation of asbestos and goods containing asbestos is a statutory requirement under Regulation 4C of the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Permission to import must be obtained before shipment to Australia.

- (b) A request for permission to import asbestos can be made at any time by writing to the Minister administering the WHS Act. Upon consideration of the request, the Minister or authorised person will reply to the applicant.
- (c) Permission to import may be granted at any period of the year.
- (d) Consideration of licence applications is effected by the Asbestos Safety and Eradication Agency. The Agency consults with the Department of Jobs and Small Business which has responsibility for the *Work Health and Safety Act 2011*. The WHS Minister is briefed by the Agency in relation to applications that are complex or not routine in nature. Otherwise, the decision maker is the CEO of the Asbestos Safety and Eradication Agency.
- (e) Confirmation of Ministerial import permission is to be available for presentation to the Australian Border Force at the point of importation.

8. Applications for permission to import asbestos are risk-assessed on a case by case basis. The act of applying for permission does not guarantee permission will be granted.

There are no specific appeal provisions in relation to asbestos available under the PI Regulations. However, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import asbestos.

Documentation and other requirements for application for licence

10. For permission to import, applications must be made in writing to the WHS Minister or to the CEO of the Asbestos Safety and Eradication Agency. The application should include the following information:

- importer's name, address and phone number, as well as those details for a representative;
- details of the asbestos or goods containing asbestos to be imported including the reason or purpose for the importation, and where the asbestos or goods good containing asbestos are to be imported from, and the amount of asbestos intended to be imported;
- details of the procedures to be used to package, label, handle, transport and dispose of the goods, including whether they are compliant with relevant laws;
- where applicable evidence that a laboratory where research will be undertaken has appropriate accreditation;
- where applicable that relevant WHS regulator approval has been obtained;
- an assurance the applicant will comply with relevant Commonwealth and state/territory legislation relating to the use of asbestos.

Relevant information for applicants is available at the website of the Asbestos Safety and Eradication Agency (Australian Government) <u>https://www.asbestossafety.gov.au/</u>.

11. The import permission of the relevant Minister or authorised person is to be available for presentation to the Australian Border Force at the point of importation. Asbestos must be declared as present in the goods when lodging the import entry.

12. No.

13. No.

Conditions of licensing

14. The WHS Minister and authorised person have discretion as to the period of validity of a licence. Generally, import permissions are single use, or multiple use, depending on the applicant's requirements, for one to two years.

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15. Not applicable.

- 16. Not transferable.
- 17. (a) Not applicable.
 - (b) The WHS Minister or authorised person may only grant permission to import asbestos:
 - in any case, for the purpose of research, analysis or display, or
 - in the case of (Australian) external territories, for disposal on the mainland.

Permission to import asbestos is granted conditional on it only being for one or more of these purposes, as specified in the permission letter. The WHS Minister or authorised person has discretion to attach other conditions, such as compliance with relevant laws in relation to asbestos.

Conditions are to ensure compliance with the asbestos border control and to reduce the risk of exposure of asbestos fibres to humans from the asbestos in the goods.

Other procedural requirements

18. In some states a person is required to seek permission to use asbestos from the relevant WHS regulator. It is a requirement that permission be sought prior to the granting of import permission.

19. Not applicable.

4 CAT AND DOG FUR PRODUCTS

Outline of System

1. The importation of cat and dog fur and goods made from or using cat or dog fur is prohibited under provisions of the *Customs Act 1901* and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) unless the permission of the Minister for Home Affairs, or an authorised person, has been obtained.

Purposes and coverage of licensing

2. The goods covered by this control include raw, tanned or processed furs or pelts, and goods that may contain such fur, that are derived from the cat and dog species listed below. These species are more commonly referred to as domestic cat and dog breeds.

- Cat fur the pelt or hair of an animal of the species Felis catus;
- Dog fur the pelt or hair of an animal of the species Canis familiaris;
- Cat or dog fur product a product or other thing that consists, wholly or partly, of cat or dog fur.
- 3. The system applies to importations from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports. The importation of cat and dog fur products is regulated in response to animal welfare concerns.

5. The control on the specified goods is a statutory requirement under Regulation 4W of the PI Regulations made under the *Customs Act 1901*. The control cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Application should be made in advance of arrival of the goods. Import permission can be considered for goods which have inadvertently arrived in Australia.
- (b) No.

- (c) No.
- (d) Permissions are granted by the Minister for Home Affairs or an authorised person. Importers may also need to approach the Department of Agriculture for permission to import cat or dog fur or products thereof.

8. Apart from statutory or ordinary requirements there are no other criteria. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the merits of the decision to the Administrative Appeals Tribunal. Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act* 1977.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply.

Documentation and other requirements for application for licence

10. Applications must be made in writing to the Minister for Home Affairs or an authorised person. The application should include the following information: importers name and address; and details of the goods to be imported.

11. The original permission from the Minister for Home Affairs or authorised person is required to be produced upon importation.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

- 14. The Minister may specify a time period for the validity of the permission.
- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Permits/licences are not transferable between importers.

17. Conditions may be imposed on the permit. Quantitative limits, where appropriate, are specified as conditions.

Other procedural requirements

18. No.

19. Not applicable.

5 CETACEANS (WHALES, DOLPHINS AND PORPOISES)

Outline of System

1. All cetaceans are listed on Appendix I or II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Under the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) all cetaceans and cetacean products are treated as if they were CITES Appendix I for the purposes of import into Australia. CITES requirements are enforced under the EPBC Act at Australian ports of entry by Home Affairs which acts on behalf of the Department of the Environment and Energy.

Purposes and coverage of licensing

- 2. All whale, dolphin and porpoise specimens are subject to control under the EPBC Act.
- 3. The system applies to specimens originating in and coming from all countries.

4. The permit system is intended to strictly regulate trade in cetacean specimens to ensure that trade is not detrimental to the survival of the species, and thereby contribute to the conservation of cetaceans. The only circumstances in which cetacean imports are allowed are:

- Non-live Appendix I listed specimens may only be moved internationally in the following circumstances: (i) if the specimen was taken from the animal prior to that species being listed under CITES; (ii) scientific research purposes; (iii) educational purposes; and (iv) exhibition purposes.
- Live Appendix I-listed specimens may only be moved internationally for conservation breeding purposes, for research and education purposes or if the specimen originated from a CITES registered commercial captive breeding program.

The system is not intended to restrict the quantity or value of imports.

5. *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act) and Environment Protection and Biodiversity Conservation Regulations 2000. It is not possible to change the system without legislative approval. The intention is to limit trade to non-commercial purposes and promote the conservation of cetaceans.

Procedures

- 6. Not applicable.
- 7. (a) Applicants should ensure required permits are in place before shipping specimens. Retrospective permits cannot be issued, and permits will not be issued once a specimen has arrived in Australia. Once a permit application is received, there is a 40-business day statutory timeframe in which a decision regarding an application must be made. When a permit is issued the specimen must be imported within six months of the issuance date.
- (b) No.
- (c) No.
- (d) Processing of international wildlife trade import permit applications is handled by the Department of the Environment and Energy. Importers may, however, have to approach other government (Commonwealth, State and Territory) agencies for approval to import due to conditions that apply to the type of item in each state or Australian Government Jurisdiction. Examples of such agencies would be the Department of Agriculture – Biosecurity [formerly known as the Australian Quarantine and Inspection Service (AQIS)], or a State Conservation Department.

8. Apart from statutory or ordinary requirements there are no other criteria. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the merits of the decision to the Administrative Appeals Tribunal. Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for licences.

Documentation and other requirements for application for licence

10. Applications for permission to import must be made electronically to the Minister for the Environment and Energy. The link to the application form can be found at: https://onlineservices.environment.gov.au/.

11. CITES documentation from the country of export is required. An Australian CITES import permit is also required unless the specimens are pre-CITES and non-live. Original documents must travel with the goods.

12. Information regarding fees and charges relating to the application for CITES import permits, and live specimen permits, are available at the Department of the Environment and Energy website at: <u>http://www.environment.gov.au/biodiversity/wildlife-trade/permits/fees</u>.

13. There is no deposit or advance payment requirement associated with the issue of licenses, other than the permit application fee (if applicable) which is payable at time of application and is not refundable, regardless of whether or not the permit is granted.

Conditions of licensing

14. CITES permits may be issued with a validity period of no more than six months. The period of validity cannot be extended.

- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Permits issued under the EPBC Act may be transferred under very limited circumstances.
- 17. (a) Not applicable.
- (b) Conditions may be imposed on the permit, and quantitative limits are specified as conditions. Conditions usually relate specifically to the nature of theimport.

Other procedural requirements

18. No.

19. Not applicable.

6 CHEESE, CERTAIN TYPES

Outline of System

1. Australia administers a tariff quota on imports of certain types of cheese and curd. Under the Cheese and Curd Quota Scheme the tariff quota applies to certain types of cheese and curd that can be imported at a concessional rate of duty (\$0.096/kg) and is restricted to 11,500 tonnes per annum. Imports can be made outside the 11,500-tonne quota allocated each year, but a higher rate of duty (\$1.220/kg) applies.

Purposes and coverage of licensing

2. No licensing system is maintained for out-of-quota cheese imports. For in-quota cheese imports, individuals or companies which have historically imported dutiable cheese under quota are allocated a share of the tariff quota, allowing them to import a quantity of cheese at the concessional rate of duty. Individuals or companies who do not have a share of the tariff quota may still import cheese at the out-of-quota tariff rate. The products covered by the tariff quota are as follows:

Number 0406	Product type Cheese and Curd	Rate of Duty
0406.10	Fresh (un-ripened or uncured) cheese, including whey cheese, and curd	\$A0.096/kg (a) \$A1.220/kg (b)
0406.20	Grated or powdered cheese, of all kinds	\$A0.096/kg (a) \$A1.220/kg (b)
0406.30	Processed cheese, not grated or powdered	\$A0.096/kg (a) \$A1.220/kg (b)
0406.40.10	Blue-veined cheese:	Free (c)
	 Roquefort, Stilton 	
0406.40.90	Blue-veined cheese:	\$A0.096/kg (a)
	– Other	\$A1.220/kg (b)

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Number 0406	Product type Cheese and Curd	Rate of Duty
0406.90.10	Other Cheese:	Free (c)
	 Cheese, of the following types: made wholly from goats' milk, other than feta or kasseri surface-ripened soft, having: 	
0406.90.90	Other Cheese:	\$A0.096/kg (a)
	– Other	\$A1.220/kg (b)
	 includes Cheddar, Colby, Edam, Gouda, Havarti, Parmesan, Kasseri, Mozzarella, Provolone, Feta 	

(a) Rate for cheese imported within the tariff quota.

(b) Out of quota rate for cheese imported in excess of tariff quota amount.

(c) Not subject to the tariff quota. Included in table only to indicate coverage of residual tariff item ("other").

3. The scheme applies to cheeses originating in and coming from all countries except some members of the Association of Southeast Asian Nations (ASEAN– Malaysia, the Republic of the Philippines, the Kingdom of Thailand, the Kingdom of Cambodia, the Lao People's Democratic Republic and the Republic of Indonesia only), a number of countries in the Trans-Pacific Partnership (TPP – Canada, Japan, Mexico, New Zealand, the Republic of Singapore and the Socialist Republic of Viet Nam only), Chile, Papua New Guinea, People's Republic of China, Republic of Korea, South Pacific Forum Island Countries, or the United States of America.

4. The licensing system is used to administer the tariff quota.

5. The licensing system is maintained under the *Customs Act 1901*, and the *Customs Tariff Act 1995*. The system cannot be abolished without legislative approval.

Procedures

- 6.-I. The names of annual tariff quota holders and their quota allocation are made public through publication in the Commonwealth of Australia Gazette.
- II. The size of the tariff quota is 11,500 tonnes per annum. The allocation of the tariff quota to individual importers occurs on an annual basis.
- III. Tariff quota allocations to individuals or companies are based on historical trade performance in the importation of cheese under quota. No tariff quota is allocated on the basis of domestic production of like product. Unused portions/amounts of the tariff quota allocation are not added to the tariff quota for the following year.

IV.-VI. Not applicable.

- VII. The Department of Home Affairs administers all aspects of the scheme.
- VIII. Tariff quotas are allocated to importers on the basis of historical trade performance involving quota usage. The allocations of the cheese and curd quota are made to importers in July each year based on the actual usage of quota to import cheese and curd in the 23 months ending 31 May of that same year. New importers are able to acquire tariff quota allocation on transfer from an existing holder of tariff quota.
- IX. Not applicable.

Note: The rate for developing countries is as shown in the table above, less 5% of the customs value (fob price) of the product.

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X. Not applicable.

XI. No.

7. Not applicable.

8. No circumstances exist for refusal to make an allocation beyond failure to meet the standard criteria.

Allocations are made only in accordance with a Determination made in pursuance of Section 273B of the *Customs Act 1901*, and published documentation such as relevant Department of Home Affairs Notices. Allocations of quota to new parties are enacted by transfer by use of an approved form.

The fixed annual amount of quota available for distribution is allocated to existing quota holders according to each quota holders' previous import history of use of quota in the 23 months ending 31 May prior to the next financial year allocation. The scheme does not provide for direct applications for quota and does not have a licensing system as such.

The Department of Home Affairs has no record of refusals to make an allocation.

All decisions of an administrative nature are appealable on a case-by-case basis under the *Administrative Decisions (Judicial Review) Act*.

Eligibility of importers to apply for licence

- 9. (a) Only those firms that have a history of trade performance in importing cheese under quota are allocated a share in the tariff quota. The allocation of the tariff quota is made on the basis of historical trade performance. Firms are free to transfer their tariff quota allocation.
- (b) Not applicable.

Documentation and other requirements for application for licence

10. Applications are not required. Eligible importers are advised of their entitlement based on the Department of Home Affairs records of import entries lodged during the preceding base period.

11. No quota specific document is required on importation. Product is entered into Australia under quota by use of unique Tariff Quota Numbers and security codes on Customs import clearance documentation (electronic or manual).

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Twelve-month period with no extensions.

15. There are no official penalties for individuals or companies that do not utilise their allocation. However, since allocations are based on historical trading performance, future allocations may be reduced for individuals or companies that do not utilise their allocation.

16. Tariff quota allocations can be transferred between individuals and companies without limitation. However, transfer transactions do <u>not</u> count as trade performance for the purpose of quota allocation.

17. (a) No.

(b) No.

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Other procedural requirements

18. No.

19. Not applicable.

7 CHEMICAL WEAPONS, CHEMICALS AND THEIR PRECURSORS

Outline of System

1. The importation into Australia of prescribed goods containing a chemical compound, or a chemical compound belonging to a group of compounds, mentioned in Part 2 or 3 of Schedule 11 of the Customs (Prohibited Imports) Regulations 1956 (PI Regulations), from a country that is not a State Party to the *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction* ("Chemical Weapons Convention"), is prohibited under Regulation 5J of the PI Regulations.

The importation of prescribed goods containing a chemical compound, or a chemical compound belonging to a group of compounds, mentioned in Part 2 or 3 of Schedule 11 of the PI Regulations from a country that is a State Party to the Chemical Weapons Convention or mentioned in Part 4 of Schedule 11 of the PI Regulations, is prohibited unless:

- the Minister for Foreign Affairs or an authorised person has given permission in writing to import the goods. The Minister has authorised the positions of Director General and Assistant Secretary of Australian Safeguards and Non-Proliferation Office (ASNO) to grant permits; and
- the permission is produced to the Australian Border Force.

These prohibitions do not apply to chemicals listed in Part 3 (except Items 1, 2 or 3) or Part 4 of Schedule 11 where they are in concentrations of less than 10% by weight of the goods, and there are no other Part 2, 3 or 4 chemical compounds in the goods. Such goods may be imported from both State Parties and non-State Parties without requiring a permit.

Purposes and coverage of licensing

2. Chemical compounds as mentioned in Part 2 or 3 of Schedule 11 of the PI Regulations from a country that is a State Party to the Chemical Weapons Convention and all Part 4 chemicals are regulated by a permit system. A permit must be granted by the Minister for Foreign Affairs or an authorised person and produced to the Australian Border Force.

3. The regulations apply to the importation of goods from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports. Australia is a Party to the Chemical Weapons Convention (CWC), and amongst other things, this treaty requires State Parties to declare trade in CWC-Scheduled chemicals, and to impose trade restrictions on transfers of the more toxic chemicals listed in Part 2 and 3 to non-State Parties. Since implementing the treaty in 1997, Australia has regulated the Part 2 chemicals through use of permits. In 2000, the permit system was extended to apply to Part 3 and 4 chemicals in response to stricter CWC provisions relating to Part 3 transfers and because less formal means of controlling and tracking were assessed as inadequate.

5. The control on importation of the specified goods is a statutory requirement under Regulation 5J of the PI Regulations made under the *Customs Act 1901*, but could also be relevant to the *Chemical Weapons (Prohibition) Act 1994*. This restriction does not apply to goods that contain a chemical compound listed in Part 3 (except Items 1, 2 or 3) or Part 4 of Schedule 11 of the PI Regulations that is less than 10% by weight of the total and contain no other listed chemicals. The system cannot be abolished without legislative approval.

Procedures

6. Not applicable.

- 7. (a) Application should be made in advance of arrival of the goods. There are two types of permits: permits for chemicals in Part 2 of Schedule 11 of the PI Regulations (Schedule 1 of the CWC) and permits for chemicals in Part 3 and Part 4 of Schedule 11 of the PI Regulations (Schedules 2 and 3 of the CWC). Chemicals from Part 2 require 37 days' notice for importation which cannot be varied due to concomitant international reporting requirements. However, the 37-day advance notification requirement is waived for imports of saxitoxin in quantities of 5 mg or less for medical/diagnostic purposes provided that the goods contain no other chemical listed in Part 2 of Schedule 11 of the PI Regulations. Permits for chemicals listed in Part 3 and Part 4 of Schedule 11 require 7 days' notice, which can be reduced if necessary.
- (b) Permits cannot be issued immediately for chemicals under Part 2 except in the saxitoxin case described in paragraph 7(a). Part 3 and 4 chemical permits can be issued immediately where practical. There is also allowance for post-import permits to be issued immediately upon request under subdivision GC of the *Customs Act 1901* where importation occurred inadvertently without a permit.
- (c) Permits may be issued at any period of the year.
- (d) Permit applications are considered by a single administrative organ, namely ASNO as the permit issuing authority. However, ASNO consults with the Department of Home Affairs prior to issuing an import permit to check whether there are any adverse findings for that company in relation to previous imports. Permits are issued by the Minister for Foreign Affairs or authorised persons (i.e. the Director General and Assistant Secretary of ASNO).

Please note that ASNO then provides the Australian Border Force with the details of import permit holders for Part 3 and 4 chemicals, including the company name, all chemicals listed on their import permit, and the tariff classification code used by the Importer (if known).

8. Application for permission to import can be refused on the discretion of the Minister for Foreign Affairs. There is no right of appeal on the merits of the decision. However, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- All persons, firms and institutions are eligible to apply for permission to import, however the (b) chemicals from Parts 2 and 3 can only be imported from a country which is a State Party to Convention the Chemical Weapons (as listed on the Internet at https://www.opcw.org/about-opcw/member-states). Also, all of the prescribed chemical imports can only be used for purposes not prohibited by the CWC, as provided for under the Chemical Weapons (Prohibition) Act 1994.

Documentation and other requirements for application for licence

10. For permission to import, applications must be made in writing to the relevant Minister or authorised person.

<u>Permits for chemicals in Part 2 of Schedule 11 of the Customs (Prohibited Imports) Regulations 1956</u> (i.e. Schedule 1 of the CWC).

The permit is valid for a single shipment of the specified chemical. The following details must be included in the application:

- importer's name, address, Australian Business Number and other contact details;
- supplier's name and address;
- country of export (this can only be another State Party) the goods must be shipped directly; transhipment through another country is not allowed;
- name, CAS number, quantity (gross and net) and percentage by weight, proposed use, tariff classification code and other descriptors of the chemical;
- date of export from supplying country and expected import date;
- end user's name, address and other contact details;

• a description of security measures that will be taken to prevent unauthorised access to the chemical.

Permits for chemicals in Part 3 and Part 4 of Schedule 11 of the Customs (Prohibited Imports) Regulations 1956 (i.e. Schedules 2 & 3 of the CWC).

The permit is valid for multiple shipments of multiple chemicals over a specified time, usually one year. The following details must be included in the application:

- importer's name, address and other contact details;
- importer's ABN or Customs Client ID;
- names, CAS numbers and percentage by weight of the chemicals the Importer is proposing to import;
- exporting country;
- a description of security measures that will be taken to prevent unauthorised access to the chemical.

ASNO's secure online portal (available for existing import permit holders since 1 January 2015) allows for electronic reporting and renewal of import permits.

Companies that are importing chemicals for the first time must submit a completed import permit application form (available at <u>https://dfat.gov.au/international-relations/security/non-proliferation-disarmament-arms-control/chemical-weapons/cwc/pages/australias-national-authority-for-the-chemical-weapons-convention.aspx).</u>

Further information, including permit application and reporting forms, is available at: https://dfat.gov.au/about-us/publications/Pages/the-chemical-weapons-convention-information-for-importers-and-exporters-of-chemicals-2014.aspx.

11. Written permission of the Foreign Minister or ASNO (i.e. the import permit) is required by the Australian Border Force at the time of import. Where Part 2 chemicals are imported, the importer must also notify ASNO of the actual arrival date within 30 days of shipment arrival in Australia.

12. No.

13. Not applicable.

Conditions of licensing

14. Permits for chemicals in Part 2 of Schedule 11 of the PI Regulations apply to one consignment only and are valid for three months. A new application is required for each import.

Permits for chemicals in Part 3 and 4 of Schedule 11 of the PI Regulations may be for multiple importations and are valid for up to 12 months. Permits may be reissued on an annual basis on request, provided all permit conditions are met, including reporting annually to ASNO on actual quantities of chemicals imported. Permits may also be varied at any time.

15. No.

16. No.

17. A permission granted under Regulation 5J of the PI Regulations may specify conditions or requirements to be complied with by the holder of the permission. Permit requirements for chemicals in Parts 3 and 4 of Schedule 11 include the annual reporting of chemical shipments covered by the permit for the previous calendar year. If the holder of any permission fails to comply with a condition or requirement the Minister may revoke the permission.

Other procedural requirements

18. For Part 2 and 3 chemicals, the recipient facility will require an operational permit under the *Chemical Weapons (Prohibition) Act 1994* if certain activity thresholds for those chemicals are

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exceeded. However, the requirements for operational permits as specified under the Act are not linked to the timing of imports.

19. Not applicable.

8 COUNTERFEIT CREDIT CARDS

Outline of System

1. The importation of counterfeit credit, debit or charge cards is prohibited under provisions of the *Customs Act 1901* and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations), unless the permission of the Minister administering the *Australian Federal Police Act 1979* – presently the Minister for Home Affairs – has been obtained.

Purposes and coverage of licensing

2. The goods covered are any non-genuine credit, debit and charge cards that are made to imitate and pass for genuine cards.

3. The system applies to any non-genuine credit, debit and charge cards that are made to imitate and pass for genuine cards originating from all countries.

4. The PI Regulations are intended to prohibit the importation of counterfeit credit, debit or charge cards.

5. The control on the specified goods is a statutory requirement under PI Regulations made under the *Customs Act 1901*. The control cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7. (a) Applications for permission to import should be made in advance of arrival of the goods.

- (b) Applications for permission to import can be processed immediately, provided all information is available and the application is considered to be urgent.
- (c) Permits may be issued at any period of the year.
- (d) Permits are granted by the Minister for Home Affairs.

8. Applications for permission to import can be refused at the discretion of the relevant Minister. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the decision-making process under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply.

Documentation and other requirements for application for licence

10. Applications must be made in writing to the Minister. The application should include the following information:

- Importers name and address;
- Details of the goods to be imported.
- 11. The original permission from the Minister or authorised person is required upon importation.
- 12. There is no licensing fee.
- 13. There is no deposit or advance payment requirement associated with the issue of these licenses.

Conditions of licensing

14. The Minister may specify a time period for the validity of the permission.

15. There is no penalty for the non-utilisation of a license or a portion of a license.

16. Permits/licenses are not transferable between importers.

17. Conditions may be imposed on the permission and quantities are specified.

Other procedural requirements

18. No.

19. Not applicable.

9 DOG COLLAR – PROTRUSION

Outline of System

1. The importation of protrusion dog collars is prohibited under provisions of the *Customs Act 1901* and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations), unless the permission of the Minister for Home Affairs, or an authorised person, has been obtained.

Purposes and coverage of licensing

2. The goods covered are: dog collars, incorporating apparatus designed to puncture or bruise an animal's skin.

3. The system applies to importations from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports. The importation of protrusion dog collars is regulated in response to animal welfare concerns.

5. The control on the specified goods is a statutory requirement under Regulation 4 Schedule 2, Item 10 of the PI Regulations made under the *Customs Act 1901*. The control cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7. (a) Application should be made in advance of arrival of the goods.

- (b) No.
- (c) No.
- (d) Permissions are granted by the Minister for Home Affairs or an authorised person.

8. Apart from statutory or ordinary requirements there are no other criteria for refusal. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the decision-making process under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) All persons, firms and institutions are eligible to apply.

Documentation and other requirements for application for licence

10. Applications must be made in writing to the Minister for Home Affairs or an authorised person. The application should include the following information:

- importer's name and address;
- details of the goods to be imported.

11. The original permission from the Minister for Home Affairs or authorised person is required to be produced upon importation.

12. There is no permit fee.

13. Not applicable.

Conditions of licensing

14. The Minister for Home Affairs may specify a time period for the validity of the permission.

15. There is no penalty for the non-utilisation of a license or a portion of a permission.

16. Licenses are not transferable between importers.

17. Conditions may be imposed on the permit. Quantitative limits, where appropriate, are specified as conditions.

Other procedural requirements

18. No.

19. Not applicable.

10 FLAGS, ARMS AND SEALS

Outline of System

1. The importation of goods with a representation of the arms, seal or flag of the Commonwealth or a State or Territory or the Royal Arms is prohibited under provisions of the *Customs Act 1901* and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations).

For goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of the Commonwealth or a representation so nearly resembling the Arms, a flag or a seal of the Commonwealth as to be likely to deceive, specified conditions must be complied with. The goods must not be imported unless the design has been approved in writing by the Secretary to the Department of the Prime Minister and Cabinet or an authorised person; and if the collector asks the importer to produce the approval, the importer produces it.

For goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of a State or Territory of the Commonwealth or a representation so nearly resembling the Arms, a flag or a seal of a State or Territory of the Commonwealth as to be likely to deceive; or a representation of the Royal Arms or a representation so nearly resembling the Royal Arms as to be likely to deceive, permission from the Minister for Home Affairs or an authorised person must be obtained.

Purposes and coverage of licensing

2. The goods covered are:

 goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of the Commonwealth or a representation so nearly resembling the Arms, a flag or a seal of the Commonwealth as to be likely to deceive; and

- goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of a State or Territory of the Commonwealth or a representation so nearly resembling the Arms, a flag or a seal of a State or Territory of the Commonwealth as to be likely to deceive; and
- goods to which, or to the coverings of which, there is applied a representation of the Royal Arms or a representation so nearly resembling the Royal Arms as to be likely to deceive.

3. The system applies to the importation of goods originating from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports.

The importation of goods bearing the arms or having applied to them a representation of a flag or seal of the Commonwealth or a State or Territory was introduced to act as a quality control measure to ensure that representations are realistic, of good quality, preserve the dignity and integrity of national symbols and do not breach other legislation.

5. The control on the specified goods is a statutory requirement under Regulation 4, Schedule 2 (State and Territory flags, arms and seals; and the Royal Arms) and Schedule 3 (Commonwealth flags, arms and seals) of the PI Regulations made under the *Customs Act 1901*.

For goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of a State or Territory of the Commonwealth, the Minister for Home Affairs requires the prior approval of the relevant State/Territory Protocol section before an import permission will be issued.

For goods to which, or to the coverings of which, there is applied a representation of the arms, a flag or a seal of the Commonwealth only the approval of the design by the Department of Prime Minister and Cabinet is required to import the goods. Importers must produce a copy of the approval to the Collection if requested.

The control cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Applications should be made in advance of the importation of the goods and it is recommended that the design be approved prior to the mass production of goods.
- (b) Permissions cannot be granted immediately on request.
- (c) Permits may be issued throughout the year.
- (d) Designs must be approved by the Department of Prime Minister and Cabinet or the relevant State/Territory protocol section and for goods listed in Schedule 2, permission to import obtained from the Minister for Home Affairs, or an authorised person.

8. Apart from statutory or ordinary requirements, the only other criteria for refusal is if the design has not been approved by the relevant authority. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the decision-making process under the *Administrative Decisions (Judicial Review) Act 1977.*

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) All persons, firms and institutions are eligible to apply for permission to import.

Documentation and other requirements for application for licence

10. Applications for permission to import goods having a representation of the arms, a flag or a seal of the Commonwealth should include:

- the importer's name and address;
- a description of the goods; and
- a copy of the design.

11. Applications for permission to import goods having a representation of State and Territory flags, arms or seals should include:

- the importer's name and address;
- a description of the goods; and
- design approval from the Premier's or Chief Ministers department in the relevant state or territory.

12. In the case of goods bearing a representation of the arms, a flag or a seal of the Commonwealth if the collector asks the importer to produce the design approval issued by Secretary to the Department of the Prime Minister and Cabinet approval, the importer must produce it.

In the case of goods bearing a representation of the arms, a flag or a seal of a State or Territory of the Commonwealth or a representation of the Royal Arms the permission from the Minister for Home Affairs or authorised person is required to be produced upon importation.

13. There is no licensing fee or administrative charge.

Conditions of licensing

14. There is no deposit or advance payment requirement associated with the issue of licenses.

15. Import permissions are not subject to a validity period. In the case of goods bearing a representation of the arms, a flag or a seal of the Commonwealth, the design approval provided by the Department of the Prime Minister and Cabinet covers multiple consignments for a period of 12 months. At the expiration of the 12-month period a new approval will need to be sought.

16. There is no penalty for the non-utilisation of a permission or a portion of a permission.

17. Permits/licences are not transferable between importers.

Other procedural requirements

18. No.

19. Not applicable.

11 HAZARDOUS GOODS

Outline of System

1. For health and safety reasons, the importation of goods deemed to be hazardous is prohibited under the *Customs Act 1901*, the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) and the *Competition and Consumer Act 2010*. Only the responsible Minister or an authorised person can grant permission to import banned goods.

Purposes and coverage of licensing

2. Goods covered under these Acts include:

Goods listed under Schedule 2 in relation to Regulation 4 of the PI Regulations:

- Cosmetic products containing more than 250 mg/kg of lead or lead compounds (calculated as lead), except products containing more than 250mg/kg of lead acetate designed for use in hair treatments.
- Erasers that resemble food in scent or appearance, that contain more than:
 - (a) 90 mg/kg of lead; or
 - (b) 25 mg/kg of arsenic; or

- (c) 60 mg/kg of antinomy; or
- (d) 75 mg/kg of cadmium; or
- (e) 500mg/kg of selenium; or
- (f) 60 mg/kg of mercury; or
- (g) 60 mg/kg of chromium; or
- (h) 1000mg/kg of barium.
- Money boxes coated with a material that contains more than 90 mg/kg of lead.
- Toys coated with a material the non-volatile content of which contains more than:
 - (a) 90 mg/kg of lead; or
 - (b) 25 mg/kg of arsenic; or
 - (c) 60 mg/kg of antinomy; or
 - (d) 75 mg/kg of cadmium; or
 - (e) 500mg/kg of selenium; or
 - (f) 60 mg/kg of mercury; or
 - (g) 60 mg/kg of chromium; or
 - (h) 1000mg/kg of barium.
- Pencils or paint brushes coated with a material the non-volatile content of which contains more than:
 - (a) 90 mg/kg of lead; or
 - (b) 25 mg/kg of arsenic; or
 - (c) 60 mg/kg of antinomy; or
 - (d) 75 mg/kg of cadmium; or
 - (e) 500mg/kg of selenium; or
 - (f) 60 mg/kg of mercury; or
 - (g) 60 mg/kg of chromium; or
 - (h) 1000mg/kg of barium.

Goods listed under Schedule 7 in relation to Regulation 4E of the PI Regulations:

• Glazed ceramic articles normally used for or in connexion with the storage or consumption of food containing lead or cadmium in an amount per volume beyond permissible levels specified in schedule 7 of the PI Regulations.

Goods listed in Regulation 4S of the PI Regulations:

• Certain cigarette lighters.

Goods listed under Schedule 12 in relation to Regulation 4U of the PI Regulations:

- Glucomannan in tablet form.
- Seat belt accessories and similar goods designed to induce and maintain slack in retractor seat beats.
- Sun visors that do not comply with Australian Design Rule No. 11.
- Victim toys.
- Chewing tobacco and snuffs intended for oral use, imported in amount greater than 1.5 kilograms.
- Underwater breathing apparatus consisting of an air pump, powered by the user's legs, that supplies air drawn down from the water's surface in a compressed state dependent on the user's effort.
- Devices that enable a water skier to be released quickly in the event of a mishap in the water.
- Candles with wicks that contain greater than 0.06% lead by weight and candle wicks containing greater than 0.06% lead by weight.
- Jelly confectionery product containing 'konjac' (also known as glucomannan, conjac, konnyaku, konjonac, taro powder and yam flour) and supplied in a container that has a height or width of less than or equal to 45mm.

3. The regulations apply to the importation of goods from all countries.

4. The PI Regulations are not intended to restrict the quantity or value of imports. The importation of these goods is regulated due to safety concerns for people and animals if the goods are used inappropriately.

5. The control on importation of the specified goods is a statutory requirement under the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

6. Not applicable.

- 7. (a) Applications should be made in advance of arrival of the goods. In certain circumstances, import permission can be given to goods that have inadvertently arrived at the point of entry.
- (b) Permission to import is granted by the responsible Minister or an authorised person.
- (c) There are no such limitations.
- (d) Permission to import is granted by the responsible Minister or an authorised person.

Importers may be required to provide written confirmation from an analytical laboratory recognised by the National Association of Testing Authorities Australia (NATA), or a NATA accredited authority, that their goods comply with the requirements of the regulations.

8. Apart from statutory or ordinary requirements there are no other criteria. Reasons for refusal are given to applicants. In certain circumstances applicants refused permission to import may appeal on the merits of the decision to the Administrative Appeals Tribunal. Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply.

Documentation and other requirements for application for licence

10. Applications for permission to import must be made to the responsible Minister or authorised person. The application must include the following information:

- Importer's name and address;
- Details of the goods to be imported, including quantity to be imported and intended use and distribution.

11. The original permission from the responsible Minister or authorised person is required to be produced upon importation.

Alternatively, for the importation of lighters under Regulation 4S of the PI Regulations, the importer may complete a statutory declaration stating that a certificate of compliance has been issued and produce that statutory declaration to the responsible customs administration.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. The responsible Minister or authorised person may specify a time period for the validity of the permission.

- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Permits/licences are not transferable between importers.

17. (a) Not applicable.

(b) Permission to import goods specified under Regulations 4, 4E, 4S and 4U of the PI Regulations may be subject to conditions regarding custody, use, disposal or distribution of the imported goods.

Other procedural requirements

18. No.

19. Not applicable.

12 HAZARDOUS WASTE

Outline of System

1. The import, export and transit of hazardous waste is regulated under the *Hazardous Waste* (*Regulation of Exports and Imports*) *Act 1989* (the Act) and associated regulations, to ensure that hazardous waste is managed in an environmentally sound manner to protect human beings and the environment, within and outside Australia.

The regulatory framework implements Australia's obligations under the *Basel Convention for the Control of Trans-boundary Movements of Hazardous Waste and their Disposal* (Basel Convention), as well as the following related agreements and arrangements concerning the transboundary movement of hazardous and other waste:

- the Organisation for Economic Co-operation and Development (OECD) Council Decision C(2001) 107 FINAL, as amended by C(2004)20;
- the Waigani Convention (Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes within the South Pacific Region); and
- a bilateral arrangement between Australia and the United Nations Transitional Administration in East Timor.

Purposes and coverage of licensing

2. The Act and regulations establish a permit control system for the export from, import into, or transit through, Australia of hazardous and other wastes, which are determined by category and characteristics listed in the schedules of the Basel Convention, Waigani Convention, and OECD Council Decision.

3. The permit system applies to all transboundary movements of hazardous and other wastes between countries that are a party to the Basel Convention or the Waigani Convention, or member countries of the OECD, or imports from East Timor to Australia.

4. The Act and regulations are not intended to restrict the quantity or value of imports.

The permit system ensures that Australia's international obligations concerning the transboundary movement, for environmentally sound and safe management of hazardous and other waste, are upheld.

To that effect, the Basel Convention provides that trans boundary movements of hazardous and other wastes is to be reduced to the minimum consistent with the environmentally sound and efficient management of such wastes.

Complementary to this, the OECD Council Decision controls the transboundary movements of hazardous and other wastes destined for recycling and/or recovery operations between OECD members in view of member countries having established infrastructure.

Australia's agreement with East Timor allows the import of hazardous waste from East Timor to Australia following similar procedures to that established under the Basel Convention.

5. The law under which the permitting system is maintained is the *Hazardous Waste (Regulation of Exports and Imports) Act 1989* and associated regulations. Permitting is a statutory requirement for the import, export and transit of any hazardous waste listed in schedules to the Basel Convention, Waigani Convention, or the OECD Council Decision. It is not possible to abolish the system without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) The Act and regulations require that a permit be obtained before hazardous waste is exported from, imported into, or transited through, Australia. All applications are assessed according to the relevant sections of the Act or regulations, and on a case by case basis. The timeframes in the Act and regulations reflect the timeframes provided for in the treaties on hazardous waste to which Australia is a party.
- (b) No. Permits are issued only after authorisation by the Minister for the Environment and Energy or their delegate, with a requirement for determination of the justification for import and the fitness of the processing organisation to treat the material in an environmentally sound manner.
- (c) No.
- (d) Consideration of a permit application is undertaken by the Department of the Environment and Energy. Importers may, however, have to approach other government (Commonwealth, State and Territory) agencies for approval to import due to conditions that apply to the type of item. Examples of such agencies would be the Australian Quarantine and Inspection Service (AQIS), Therapeutic Goods Administration or the appropriate State or Territory environment agency.

8. A permit application may be refused on various grounds under the Act and regulations, for example if the Minister considers that it would not be in the public interest to grant the permit.

There are also requirements on all countries through which the proposed movement of hazardous waste is to be transported, to control the transboundary movement of hazardous waste. Refusal to accept the movement by any such country will result in the country of export being refused a permit.

A statement of reasons for the Minister or their delegate's refusal of a permit is given to applicants. Applicants refused permission to exports may appeal to the Administrative Appeals Tribunal on the merits of the decision. Alternatively, an appeal may be made on the decision- making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) Any person, firm or institution may apply for a permit.

Documentation and other requirements for application for licence

10. As with all applications, the decision of the Minister or their delegate will be based on information provided as required under the Act or relevant regulations.

Amongst other things, the Minister will consider whether the proposed manner for dealing with the hazardous waste is environmentally sound, the applicant is a suitable person to be granted a permit and has appropriate insurance.

The form that is required to be used when applying for an import, export or transit permit may be accessed here: <u>http://www.environment.gov.au/protection/hazardous-waste/applying-permit</u>.

In general information required in the permit application includes:

- the identity and suitability of the applicant, including applicant's name and address and financial situation;
- a description of the material to be imported;
- the method of transportation, ports of entry for importation; and
- the method of disposal of the waste.

More details of what the Minister will give consideration to as part of an application process can be found at: <u>https://www.comlaw.gov.au/Series/C2004A03937</u>

Additional documentation required with the application includes verification that the disposal is environmentally sound and safe, the capability of the processors to treat the material, and proof that appropriate insurances and contracts have been obtained/arranged.

11. The import permit and a completed Movement/Tracking Form are required.

12. The application fees and levy that apply to the lodgement of permit applications, as at 1 July 2017, are outlined in the below schedule of fees and can also be accessed in the *Hazardous Waste* (*Regulation of Exports and Imports*) (*Fees*) *Regulations* 1990. All permit application fess (including the levy) are non-refundable.

Application type	Fee (AUD)	Levy (AUD)	Total
1 Transit permit	\$5,225	\$4,616	\$9,841
2 Import permit	\$7,088	\$4,616	\$11,704
3 Export permit—for operations which may lead to resource recovery, recycling, reclamation, direct re-use or alternative uses (within the meaning of the Basel Convention)	\$12,667	\$4,616	\$17,283
4 Export permit—for operations other than those which may lead to resource recovery, recycling, reclamation, direct re-use or alternative uses (within the meaning of the Basel Convention)	\$35,035	\$4,616	\$39,651
5 Transit permit—variation	\$2,244	n/a	\$2,244
6 Import permit—variation	\$2,616	n/a	\$2,616
7 Export permit—variation of export permit granted for operations which may lead to resource recovery, recycling, reclamation, direct re-use or alternative uses (within the meaning of the Basel Convention)	\$5,970	n/a	\$5,970
8 Export permit—variation of export permit granted for operations other than those which may lead to resource recovery, recycling, reclamation, direct re-use or alternative uses (within the meaning of the Basel Convention)	\$14,913	n/a	\$14,913

Notes:

Source: Hazardous Waste (Regulation of Exports and Imports) (Fees) Regulations 1990.

The Minister may determine in writing that the prescribed fee payable in relation to a specified application or a specified notice is reduced by a specified amount.

• From 1 July 2018, the application fees and levy is indexed annually according to the CPI. This is the final stage of a two-stage process to move to full cost recovery for hazardous waste permits. The first stage was implemented on 1 July 2016 and increased permit application fees to achieve an estimated 33 percent cost recovery.

13. There is no requirement for an advance payment, as the relevant fee must be paid at the time of making a permit application. Full payment of the fee is required (unless the Minister has determined in writing that the prescribed fee payable in relation to a specified application or a specified notice is reduced by a specified amount) - The fee is not refundable.

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Conditions of licensing

14. Under the Basel Convention, the import permit is valid for a period of up to twelve months and covers the amount and number of shipments of the hazardous waste as noted in the application. The OECD Council Decision allows the period for permits up to 36 months for pre-authorised facilities.

- 15. There is no penalty for the non-utilisation of an import permit or a portion of that permit.
- 16. Permits/licences are not transferable between importers.
- 17. (a) Not applicable.
- (b) All applications must identify the maximum amount of the hazardous wastes that is intended to be covered by the permit. The maximum amount that is then specified in that permit cannot be exceeded. In addition, the applicant is provided with conditions that form part of the permit that usually relate specifically to the transport, treatment and/or disposal of the hazardous waste.

Other procedural requirements

18. In some cases the approval/certification of other agencies is required prior to the issue of a permit. The permit applicant is responsible for ensuring they have obtained all relevant approvals and licenses.

19. Not applicable.

13 ICE PIPES

Outline of System

1. The importation of Ice Pipes is prohibited under provisions of the Customs Act 1901 and the <u>Customs (Prohibited Imports) Regulations 1956</u> (PI Regulations) unless the permission of the Minister for Home Affairs, or an authorised person, has been obtained.

Purposes and coverage of licensing

2. Ice Pipes are defined as a device that is capable of being used for administering methylamphetamine, or any other drug mentioned in Schedule 4, by the drawing or inhaling of smoke or fumes resulting from heating the drug, in the device, in a crystal, powder, oil or base form. Components are also controlled and these are defined as a device which appears, on reasonable grounds, to be part of an ice pipe; and is capable of being used for administering a drug mentioned in Schedule 4, in the way described in the definition of ice pipe, only if adjusted, modified or added to.

3. The system applies to the importation of goods originating from all countries.

4. The PI Regulations are not intended to restrict the quantity or volume of imports. A permit can specify conditions or requirements including times for compliance and the number of Ice Pipes allowed to be imported. The Minister or an authorised person has the power to revoke permission where the holder does not comply with a condition or requirement.

The control on ice pipes has been introduced as a result of the Australian Government's commitment to reduce the abuse of illicit drugs. Amphetamine Type Stimulants (ATS) have been identified by the Australian Criminal Intelligence Commission as an organised crime priority for the Australian Government. While ATS can be administered in a range of ways, smoking its crystalline form (known as ice) is particularly dangerous, due to high drug purity levels, which can result in serious physical and emotional harm.

5. The control on the specified goods is a statutory requirement under Regulation 4I of the PI Regulations made under the *Customs Act 1901*. The control cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7. Where there is no quantitative limit on importation of a product or on imports from a particular country:

- (a) Application should be made in advance of arrival of the goods.
- (b) Applications for permission to import can be processed immediately provided all information is available and the application is considered to be urgent.
- (c) Permits may be issued at any period of the year.
- (d) Permissions are granted by the Minister for Home Affairs or an authorised person.

8. Application for permission to import can be refused at the discretion of the relevant Minister or authorised person. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal on the decision-making process under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply. However, permission will not be granted for personal use.

Documentation and other requirements for application for licence

10. Applications must be made in writing to the Minister for Home Affairs or an authorised person. The application should include supporting documentation to possess the goods and/or any relevant end user evidential documentation.

- 11. The original permission from the Minister or authorised person is required upon importation.
- 12. There is no permit fee.
- 13. There is no deposit or advance payment requirement associated with the issue of permission.

Conditions of licensing

- 14. The Minister may specify a time period for the validity of the permission.
- 15. There is no penalty for the non-utilisation of a permission or a portion of a permission.
- 16. Permits/licenses are not transferable between importers.
- 17. Conditions may be imposed on the permission and quantities are specified.

Other procedural requirements

18. No.

19. Not applicable.

14 IMPORTS TO ANTARTICA

Outline of System

1. Under the Antarctic Treaty (Environment Protection) Act 1980 as amended, and in line with the requirements of the Protocol on Environmental Protection to the Antarctic Treaty (the Madrid Protocol), persons are not permitted to import certain items into Antarctica. This legislation

applies to Australian nationals for all areas south of 60° south and for foreign nationals to the Australian Antarctic Territory only.

Purposes and coverage of licensing

2. The import licensing system is implemented via the *Antarctic Treaty (Environment Protection) Act 1980.* It provides:

- that a person shall not bring into the Antarctic an organism that is not indigenous to the Antarctic unless the organism (not being a live animal) was brought into the Antarctic to be used as food. None of these items may be brought into Antarctica unless authorised by a permit (s19(1)(c));
- if a person brings an organism into the Antarctic for use as food the person must put controls in place to ensure that the organism does not escape into the Antarctic environment;
- a person who brings into the Antarctic poultry or any other bird product that is to be used as food must ensure it is not contaminated with disease;
- that a person shall not bring into, or keep in, the Antarctic non-sterile soil, or polychlorinated biphenyls, or polystyrene beads or chips or any similar kind of packaging material (s19(1)(ca)); and,
- that a person shall not bring into, or keep in, the Antarctic any pesticide unless for scientific, medical or hygienic purposes (s19(1)(cb)).

3. The system applies to goods from all countries.

4. The above restrictions have been put in place to implement the Madrid Protocol. The objective of the Madrid Protocol is the comprehensive protection of the Antarctic environment and its dependent and associated ecosystems.

The Antarctic Treaty (Environment Protection) Act 1980 is not intended to restrict the quantity or value of imports.

5. The Antarctic Treaty (Environment Protection) Act 1980 may not be repealed without legislative approval.

Procedures

6. Not applicable.

- 7. (a) Proponents are encouraged to submit permit applications as far in advance of their intended activity as practicable. Proponents should allow a minimum of two months for the assessment of a permit application.
- (b) Permits cannot be granted immediately upon request. The permit-holder must obtain a permit prior to their arrival in Antarctica. Permits cannot be issued retrospectively.
- (c) Permit applications may be lodged at any time of the year.
- (d) Permit applications are assessed by one organisation i.e. the Australian Antarctic Division (AAD) of the Commonwealth Department of the Environment and Energy. Corresponding permits are also prepared by the AAD. Accordingly, proponents need only approach one organisation.

8. An application for a permit will only be refused if it does not meet the ordinary criteria. Particulars of refusals to grant permits are provided to the applicant and those particulars are accompanied by a statement to the effect that, subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal for the review of the merits of a decision to refuse to grant a permit by or on behalf of the person or persons whose interests are affected by the decision. Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

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Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) All Australian proponents of Antarctic activities are eligible to apply for a permit. No fee is charged.

Documentation and other requirements for application for licence

10. The project proponent (in the case of research projects, the Chief Investigator) completes an application form for a permit. The application should include the following information:

- name and address of applicant;
- research location and research methodology;
- any non-indigenous species being introduced to Antarctica;
- intended access to specially protected areas; sample specimens to be extracted;
- members of research team or field project; and
- organisation affiliated to research project.

Permits are applied for online. The process is described at: <u>http://www.antarctica.gov.au/environment/environmental-impact-assessment-approvals-and-permits</u>

11. Inspectors appointed under the Act monitor actions to ensure they are undertaken in accordance with the approved permit.

12. There is no fee or administrative charge.

13. Not applicable.

Conditions of licensing

14. A permit's period of validity is dependent on a project's planned length. A proponent may apply to extend a permit's period of validity.

15. There is no penalty for the non-utilisation of a permit or a portion of a permit.

16. Permits are not transferable. However, a permit may be varied to:

- include additional names; and
- omit existing names.

A person to whom a permit has been granted (a principal) may authorise other persons to accompany one or more of the principals to carry on activities authorised by the permit.

17. No.

Other procedural requirements

- 18. There are no other administrative processes required.
- 19. Not applicable.

15 IMPORTS TO TERRITORY OF HEARD ISLANDS AND MCDONALD ISLANDS

Outline of System

1. The Territory of Heard Island and McDonald Islands is an external territory of Australia. The purpose of the *Territory of Heard Island and McDonald Islands Environment Protection and Management Ordinance 1987* is the preservation and management of the Territory for the protection of its environment and wildlife.

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Purposes and coverage of licensing

2. The Territory of Heard Island and McDonald Islands Environment Protection and Management Ordinance 1987 prohibits:

- the importation of any diseased organism or live poultry into the Territory (s13);
- the importation of any organism, or any dead poultry or poultry products into the Territory unless in accordance with a permit (s14.1(b)).

3. The system applies to goods from all countries (and from other parts of Australia).

4. The *Territory of Heard Island and McDonald Islands Environment Protection and Management Ordinance 1987* is not intended to restrict the quantity or value of imports.

5. The *Territory of Heard Island and McDonald Islands Environment Protection and Management Ordinance 1987* may not be repealed without legislative approval.

Procedures

6. Not applicable.

- 7. (a) Proponents are encouraged to submit permit applications as far in advance of their intended activity as practicable. Proponents should allow four months for the assessment of a permit application.
- (b) Permits cannot be granted immediately upon request. The permit-holder must obtain a permit prior to their arrival in the Territory. Permits cannot be issued retrospectively.
- (c) Permit applications may be lodged at any time of the year.
- (d) Section 15(1) permit applications are assessed by a single organisation i.e. the Australian Antarctic Division (AAD) of the Commonwealth Department of the Environment and Energy. Corresponding permits are also prepared by the AAD. Accordingly, proponents need only approach one organisation.

8. An application for a permit will be refused if it is inconsistent with the requirements of the *Heard Island and McDonald Islands Marine Reserve Management Plan 2014-2024*, which includes the Territory. The reasons for refusals are given to the applicant and the applicant has a right of appeal. Particulars of refusals to grant permits are published in the Commonwealth Government Gazette and those particulars are accompanied by a statement to the effect that, subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal for the review of the merits of a decision to refuse to grant a permit by or on behalf of the person or persons whose interests are affected by the decision. Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) Any person is eligible to apply for a permit to import into the Territory.

Documentation and other requirements for application for licence

10. The application should include the following information:

- name and address of applicant;
- details of research location;
- any non-indigenous species being introduced to the Territory;
- use of radioisotopes;
- details of sample specimens to be extracted;
- members of research team or field project; and

• organisation affiliated to research project.

11. Permit requirements and the application process are described at: <u>http://heardisland.antarctica.gov.au/protection-and-management/management-plan/permits</u>. Visitor self-regulation is an important component of the Territory's environmental management regime.

12. No fees or administration charges are currently imposed. Section 15(6) does, however, provide for the imposition of a permit issue fee not exceeding A\$50.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. A permit's period of validity is dependent on the length of time that the applicant is scheduled to stay in the Territory. A proponent may apply to extend a permit's period of validity.

15. There is no penalty for the non-utilisation of a license or a portion of a license.

16. Permits are not transferable. However, a permit may be varied to:

- include additional names; and
- omit existing names.

17. No.

Other procedural requirements

18. There are no other administrative processes required.

19. Not applicable.

16 INCANDESCENT (FILAMENT) LAMPS

Outline of System

1. Import licensing is part of an overall policy to phase-out inefficient incandescent lighting as part of Australia's efforts to reduce energy consumption and greenhouse gas emissions. The prohibition was brought into effect in advance of point of sale restrictions for these products. Note that as no incandescent lighting of this type is manufactured in Australia this is an effective means of implementing the phase-out. The Licensing system is administered by the Appliance and Building Energy Efficiency Branch, Department of Environment and Energy, (energyrating@environment.gov.au, Ph. 61 1800 770 161).

Purposes and coverage of licensing

2. The Customs (Prohibited Imports) Regulations 1956 (PI Regulations), Regulation 4VA relates to the prohibition of certain incandescent lamps without written permission from the Minister responsible for the Department of the Environment and Energy or authorised person.

The licensing scheme covers inefficient GLS electric filament lamps as set out in Australian Standard 4934.2(Int):2008- Incandescent Lamps for General Lighting Services, Part 2: Minimum Energy Performance Standards (MEPS) Requirements.

Incandescent General Lighting Service Lamps (GLS) have the following attributes:

- (a) Shapes: A50-A65, PS50-PS65, M50-M65, T50-T65 (as generally outlined inIEC 60630) or E50-E65.
- (b) Caps: E14, E26, E27, B15 or B22d.
- (c) Nominal voltage ≥220 V.
- (d) Nominal wattage <150 W.
- (e) Not including primary coloured lamps.

Under the Combined Australian Customs Tariff Nomenclature and Statistical Classification (incorporating the WCO's Harmonized Commodity Description and Coding System) the controlled goods are classified to 8539.22.00 statistical codes 32 and 33.

The Standard specifies that it does not apply to appliance lamps, special purpose lamps and automotive lamps.

3. The system applies to goods from all countries.

4. Permissions will only be granted in a limited number of circumstances – these have been given in cases where effective and efficient lighting alternative lighting products are not available for important applications such as aircraft navigation signal lighting. The standards are not intended to restrict the quantity or value of imports.

5. Australian Customs Notice No. 2009/04 published in February 2009.

http://www.border.gov.au/Importingandbuyinggoodsfromoverseas/Documents/acn 2009 04 light globes september 2014 000.pdf

This system was put into place by virtue of regulations published on the Australian Government's Federal Register of Legislative Instruments website on 18 December 2008. The system took effect on 1 February 2009.

Procedures

- 6. Not applicable.
- 7. Processing normally takes two to three weeks.

8. No applications have been refused to date however an application for import that did not provide evidence of an essential need for a prohibited lamp; and / or concerned the import of lamps for which an effective and efficient alternative was available may be refused.

Eligibility of importers to apply for licence

9. All persons are eligible to apply for licenses.

Documentation and other requirements for application for licence

10. Not applicable.

11. Applicants may contact the Department of the Environment and Energy in relation to a proposed import. Applicants are asked to provide information regarding the products proposed to be imported, the intended use of the products and why this use cannot be satisfied by using other available lighting products. Applicants are also required to provide information on the quantity of products, number of import events and duration. Permission is required from the Minister prior to importation.

12. No fees are charged.

13. No deposit or advanced payment.

Conditions of licensing

14. Licences are not extended, however persons are able to apply for a further permission for a further period.

15. There is no penalty for non-utilization of a license.

16. Licences are intended for the applicant only.

17. Not applicable.

Other procedural requirements

18. As part of the approval importers are instructed that product packaging must include the specification "Not for Domestic Use". A licence number is provided for reference in Customs procedures.

19. There are no licence fees.

17 INDUSTRIAL CHEMICALS

Outline of System

1. Within the Department of Health, the Office of Chemical Safety (OCS) administers the statutory scheme known as the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), established under the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act). NICNAS aids in the protection of the Australian people and the environment by assessing risks from the introduction and use of industrial chemicals. Industrial chemicals include a broad range of chemicals used in inks, plastics, adhesives, paints, glues, solvents, cosmetics, soaps and many other products. OCS assessments inform decisions made by a wide range of Commonwealth, State and Territory government agencies involved in regulating the control, use, release and disposal of industrial chemicals. NICNAS administers the following licensing systems under the ICNA Act:

- new chemical assessments and authorisations requiring commercial importers and/or manufacturers to notify industrial chemicals that are new to Australia for assessment and issuing assessment certificates and permits authorising import of these chemicals
- Registration of introducers establishes a Register of Industrial Chemical Introducers A certificate of Registration authorises companies and persons to import new and existing industrial chemicals into Australia
- International conventions is responsible for implementing the domestic obligations of the Rotterdam Convention for industrial chemicals. Australia's import decisions for industrial chemicals listed in Annex III of the Convention reflects the current regulatory status of that chemical in Australia. More information can be obtained from: <u>https://www.nicnas.gov.au/about-us/international-%20obligations/Rotterdam-convention</u>.

Rotterdam Convention - The importation of polychlorinated biphenyls (PCBs), and other substances obtained by chlorinating terphenyls (PCTs) and other polyphenyls, is prohibited under the provisions of the Customs Act 1901 and Prohibited Import (PI) Regulations unless the permission in writing of the responsible Minister is granted and presented at the time of importation. The permission must be issued in the name of the owner. It may include strict conditions as to the application, disposal and destruction of the industrial chemicals.

Under the Industrial Chemicals (Notification and Assessment) Regulations1990, the importation of chemicals listed in regulation 11C(e) to (l) is prohibited without approval from the Director, NICNAS.

From 1 July 2020, a new regulatory scheme known as The Australian Industrial Chemicals Introduction Scheme (AICIS) will commence under the Industrial Chemicals Act 2019 (IC Act). The main purpose of the new scheme will remain the same as NICNAS — to help protect the Australian people and the environment by assessing the risks of industrial chemicals and providing information and recommendations to promote their safe use. Under AICIS, the activities relating to licensing systems will be (in the main) similar to those under NICNAS (see above for details).

Purposes and coverage of licensing

2. Refer above for details of each licensing system and chemicals that are subject to each system under the ICNA Act.

3. New chemical assessment and authorisation applies to the importation of industrial chemicals (as defined in the ICNA Act) from all countries.

Registration of introducers applies to all Australian persons who introduce relevant industrial chemicals (as defined in the ICNA Act). Imports can be from all countries.

International conventions – Rotterdam applies to chemicals subject to the Convention originating in and coming from countries that are Parties to that Convention. NICNAS also authorises chemicals imported from countries which are not a Party to the Convention, for example tetraethyl lead.

4. New chemical assessment and authorisation - the purpose of the notification and assessment process is to ensure that no new chemicals (those not listed on the national inventory) are introduced into Australia unless they have been assessed for risks to public health, occupational health and safety and the environment and the authority to import is granted by issuance of a certificate or permit (a limited number of statutory exemptions apply).

Registration of introducers – registering all introducers is a legislative requirement under the ICNA Act, 1989.

Every person who introduces an industrial chemical in Australia must be registered. Non-compliance is an offence for which penalties apply. The reason for the introduction of NICNAS registration is to achieve full cost-recovery of NICNAS's assessment activities. Other benefits of registration for small business includes better access to the broader industry through listing on Company Registration, and better access to information through NICNAS's compliance program.

International conventions - the purpose of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm. Systems for chemicals covered by the Rotterdam Convention apply to goods originating in and coming from countries that are Parties to that Convention. NICNAS also authorises chemicals imported from countries which are not a Party to the Convention, for example tetraethyl lead. The licensing of chemicals covered by the Rotterdam Convention is for the purpose of fulfilling Australia's obligations under that Convention. The monetary value is not a criterion for control.

Certain industrial chemicals including polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls are all considered to be persistent organic pollutants. PCBs, PCTs and polychlorinated polyphenyls are used in electrical appliances (such as transformers and capacitors), as coolants (often in light fittings), hydraulic fluids, plasticisers and dye carriers. The importation of PCBs, PCTs and polychlorinated polyphenyls is regulated as a community protection measure under the Stockholm Convention. These chemicals are considered to be highly toxic and virtually indestructible and a considerable danger to the environment. The Australian and New Zealand Environment Conservation Council (ANZECC) prepared the Australian PCBs Management Plan in 1996. The aims of the plan are the phasing out, disposal and destruction of PCBs. The Industrial Chemicals (Notification and Assessment) Act 1989 is not intended to restrict the quantity or value of imports.

5. New chemical assessment and authorisation - the registration process and the control on the importation of other industrial chemicals are prescribed in the ICNA Act 1989 and IC Act 2019.

Registration of introducers – the purpose of registering all introducers is a legislative requirement under the ICNA Act 1989 and the IC Act 2019. The risk from the importation of chemicals is borne by industry in the form of a fee based on the amount of chemical imported/manufactured.

International conventions - the licensing of chemicals covered by the Rotterdam Convention is for the purpose of fulfilling Australia's obligations under that Convention. The monetary value is not a criterion for control. The control on importation of PCBs, PCTs and polychlorinated polyphenyls is a statutory requirement under Regulation 4AB of the PI Regulations made under the Customs Act 1901.

Procedures

- 6. Not applicable.
- 7. (a) New Chemical assessment and authorisation new chemicals certificates and permits (authorising instruments) must be obtained before the chemical is introduced into Australia.

Registration of introducers – registration must be in place for companies and individuals before industrial chemicals are imported. The registration process required for individuals and

companies intending to import relevant industrial chemicals may take up to 30 days. Subject to section 80A and 80B of the Industrial Chemicals (Notification and Assessment) Act 1989, the Director (of NICNAS) must deal with an application for registration, or renewal of registration, as follows: (a) if the application is in relation to the registration year in which the application is made or a previous registration year—as soon as practicable but, in any case, within 30 days after receipt of the application; and (b) if the application is in relation to the next registration year—as soon as practicable but, in any case, not later than the later of: (i) 30 days after the start of that next registration year; and (ii) 30 days after receipt of the application.

International conventions – for the importation of polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls application for a permit should be made in advance of the arrival of the goods.

(b) New Chemical assessment and authorisation – exemptions can be issued upon application as long as the introducers meet the relevant statutory criteria. Permits and Certificates are issued after an assessment is completed Statutory timeframes apply to new chemicals assessments.

Registration of introducers - immediately as long as criteria are met.

International conventions – for the importation of polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls permits cannot be issued immediately as they are only issued on the advice of the Department of the Environment and Energy.

For the remaining chemicals listed on the Rotterdam Convention importers are advised to allow at least ten business days for written approval from the Director, NICNAS.

- (c) All licencing may be issued throughout the year.
- (d) International conventions for the importation of polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls, a permit is issued by the Minister for Home Affairs on the advice of the Department of the Environment and Energy. Permissions to import PCBs are normally granted by the Department of Home Affairs for research purposes. However, PCB waste may also be imported under the Hazardous Waste (Regulations of Exports and Imports) Act 1989, provided all the requirements of that Act have been met

For the remaining industrial chemicals listed on the Rotterdam Convention, written approvals are issued by NICNAS.

8. International conventions – for the importation of polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls an application for permission to import can be refused on the discretion of the Minister for Home Affairs or an authorised person. There is no right of appeal against the Minister's decision. For the remaining chemicals listed in the Rotterdam Convention, approvals are issued by NICNAS and there is no right of appeal against a decision by the Director not to issue an approval. However, applicants may appeal on the decision-making process itself under the Administrative Decisions (Judicial Review) Act 1977.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import provided statutory requirements outlined above are met.

Documentation and other requirements for application for licence

10. New Chemical assessment and authorisation – a comprehensive list of documentation and other requirements required for this process can be found on the NICNAS website at https://www.nicnas.gov.au/notify-your-chemical/types-of-assessments.

Registration of introducers – NICNAS Registration forms for companies and individuals that import or manufacture relevant industrial chemicals can be found at: <u>https://www.nicnas.gov.au/register-your-business</u>.

International conventions – applications for permits to import polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls must be made in writing to the Minister for Home Affairs. The application should include the importer's name and address and details of the goods to be imported.

11. International conventions – for the importation of polychlorinated biphenyls (PCBs), polychlorinated triphenyls (PCTs) and polychlorinated polyphenyls, the written permission of the Minister for Home Affairs is required to be produced on import. For the remaining chemicals listed in the Rotterdam Convention, authorisation from NICNAS is required to be in force at the time of importing the chemical.

12. A comprehensive list of all NICNAS fees and charges can be found on the NICNAS website at https://www.nicnas.gov.au/fees.

International conventions – There are fees for import approvals for chemicals listed in the Rotterdam Convention under the Industrial Chemicals (Notification and Assessment) Act 1989. The fees and charges are available at: <u>https://www.nicnas.gov.au/fees#Rotterdam</u>.

13. There is no deposit or advance payment requirement associated with the issue of licences.

Conditions of licensing

14. Registration of introducers - NICNAS Registration is valid for one year commencing on 1 September and finishing on 31 August.

International conventions - Rotterdam Permits (granted by the Minister for Home Affairs or an authorised person) apply to one consignment only.

15. There is no penalty for the non-utilisation of a licence or a portion of a licence under the ICNA Act.

16. Registration of introducers - permits/licences are not transferable between importers. Except as set out in subsections (2), (3) and (4) of 80R of the Industrial Chemicals (Notification and Assessment) Act 1989, the registration of a person is not transferable, that is:

- (2) If a registered person dies, the legal personal representative of the person's estate becomes the registered person for the purposes of this Act.
- (3) If a registered person becomes bankrupt, the trustee of the estate of the bankrupt becomes the registered person for the purposes of this Act.
- (4) If a body corporate that is registered is being wound up, the person appointed to be the liquidator of the body corporate becomes the registered person for the purposes of this Act.

17. All authorisations to import the chemicals listed in the Rotterdam Convention can be subject to conditions including the quantity. Permission granted under Regulation 4AB of the PI Regulations may specify conditions or requirements to be complied with by the holder of the permission.

Other procedural requirements

18. No.

19. Not applicable.

18 MOTOR VEHICLES

Outline of System

1. Importation into Australia of new and used road motor vehicles is controlled under the *Motor Vehicle Standards Act 1989* (MVSA) and the Motor Vehicle Standards Regulations 1989 and Determinations until 10 December 2019. Importation into Australia and provision of new and used road motor vehicles will be controlled under the Road Vehicle Standards Act 2018 and the Road Vehicle Standards Rules 2019 and Determinations from 10 December 2019.

Purposes and coverage of licensing

2. Approvals are required for all road motor vehicles imported into Australia.

3. The *Motor Vehicle Standards Act 1989* (the Act), the Motor Vehicle Standards Regulations 1989 (The Regulations), Determinations and Australian Design Rules (ADR), apply to the importation of all new and used road vehicles from all countries.

4. Importation of new and used vehicles that do not meet relevant ADRs is restricted and subject to controls to ensure that Australian safety and environmental standards are not compromised.

The Department of Infrastructure, Regional Development and Cities administers the Act and applies national standards for new and some used road motor vehicles. In practical terms, these standards deliver levels of vehicle safety and environmental performance that are generally expected by the Australian community. The standards are recognised as contributing towards safer roads and cleaner air.

Under the Act and the Regulations, several concessional arrangements also exist to allow the limited importation of used vehicles that may not meet all of the Australian Design Rules (ADRs). These options are outlined on the Department of Infrastructure, Regional Development and Cities' website, at: <u>https://www.infrastructure.gov.au/vehicles/imports/</u>.

In addition to these concessional options, the Registered Automotive Workshop Scheme (RAWS) is the primary mechanism for the import of used vehicles that are specialist and enthusiast in nature. A general introduction to the scheme is available from the Department of Infrastructure, Regional Development and Cities' website at http://raws.dotars.gov.au/index.htm.

5. Legislative requirements are set out in the Act and the Regulations and associated Determinations. Controls on the import of vehicles are statutory requirements and cannot be abolished without legislative approval.

Procedures

- 6. I. As identified above, information about the requirements and procedures for applying for a vehicle import approval is published on the Department's website: https://www.infrastructure.gov.au/vehicles/imports/ or can be supplied to applicants upon request to the Department of Infrastructure, Regional Development and Cities. Attention is also drawn to the requirements for approvals through other government agencies, such as the Department of Home Affairs. Information is also readily available from shipping and customs agents and Australian diplomatic posts around the world.
- II. Restrictions are applied to individuals importing used road vehicles in commercial quantities through the Registered Automotive Workshop Scheme (RAWS). There is no limit on the number of individuals that may be licensed; the only restriction is on the individual importer. The current licence period for a Registered Automotive Workshop (RAW) is two years.

Returning Australian citizens and migrants arriving in Australia to remain permanently may import their vehicle if they comply with the requirements set out in regulation 13 of the Motor Vehicle Standards Regulations 1989. There is a restriction of one vehicle every five years to eligible persons. There are no restrictions on the importation of vehicles that comply with Australian Design Rules (i.e. that are 'standard' vehicles). III. Import approvals are not dependent on whether an applicant is a domestic producer of like goods. Approvals are issued on the basis of prescribed circumstances set out in the Regulations. There is no follow-up action taken if a vehicle is not imported following the issue of an import approval.

The names of individuals who have been issued with import approvals are not made available to governments and export promotion bodies of exporting countries upon request. This information is subject to Australian information privacy legislation and can only be released if information privacy requirements are met.

- IV. Not applicable.
- V. Applications are usually assessed within 20 business days. However, this processing time will be longer if the submitted application is incomplete or all relevant supporting documentation is not provided.
- VI. Not applicable.
- VII. Under the requirements set out in regulation 13 of the Regulations, imports of previously owned vehicles are restricted to Australian citizens or permanent migrants. Importers and permanent migrants must meet relevant customs and visa requirements of the Department of Home Affairs.
- VIII. For used vehicles imported in commercial quantities, each applicant on satisfying the legislative provisions, may import not more than 130 eligible vehicles per vehicle category (e.g. passenger car, off road vehicle, light commercial vehicle etc.) per year. New importers are required to satisfy the provisions of the Act and the Regulations before a licence is issued. Applications are examined on receipt.
- IX. Not applicable.
- X. Not applicable.
- XI. The Act includes provisions to allow the importation of vehicles imported for export that do not meet Australian Design Rules. These vehicles may not be used in transport or on public roads, nor are they allowed to be sold in the domestic market and must be exported.
- 7. (a) Applications are usually assessed within 20 business days. However, the actual processing time will depend on the completeness of the application, the type of approval being processed and the complexity of the information provided in support of an application.
- (b) Requests for immediate granting of approvals may be submitted for consideration, providing all statutory requirements are met.
- (c) There are no limitations on the period of the year for the submission of applications.
- (d) The Department of Infrastructure, Regional Development and Cities administers the vehicle import approval process. However, issues relating to immigration and quarantine must be dealt with through the relevant agencies (Department of Home Affairs and the Department of Agriculture).

8. There are no circumstances under which applications for import approval are refused other than failure to meet the statutory criteria in the Act, the Regulations, and Determinations. Reasons are provided to the applicant where a refusal is issued.

Applicants may appeal any decision to the Administrative Appeals Tribunal (AAT). Alternatively, an appeal may be made on the decision-making process itself under the *Administrative Decisions* (Judicial Review) Act 1977.

Eligibility of importers to apply for licence

9. All persons, firms/companies and institutions may apply for approval to import vehicles. The granting of an approval is dependent on whether the applicant and the vehicle(s) meet the applicable criteria under the Act and Regulations.

(a) Under regulation 13 of the Regulations (personal import arrangements) a person, who is an Australian citizen or an Australian permanent resident, or has applied to become an Australian citizen or an Australian permanent resident, may apply for approval to import a vehicle that they have owned and it was available for use for a continuous period of at least 12 months, where they have not imported another personal vehicle within the previous 5 years.

Where a vehicle is to be imported and used exclusively for racing or rallying purposes an application for import approval must be made. Approval will be granted where it is established that the vehicle is solely for racing purposes and for a particular event and/or is imported by a person holding an appropriate recognised racing licence.

Applications for import approvals for used imported vehicles can also be submitted by approved Registered Automotive Workshops, or by a workshop importing one vehicle in the initial process of becoming an approved workshop. Workshops must be a company in Australia, or have an appointed company in Australia as a sponsor.

(b) Applications can be made for import approval of new standard vehicles, for example, new vehicles complying with Australian Design Rules or new vehicles that are to be modified to comply with the Australian Design Rules by the person(s) or organisations that have been issued with Identification Plate Approvals for the make and model of the vehicles being applied for. The numbers of vehicles imported under these import approvals are not restricted.

There are no restrictions on the applicant or the number of vehicles that can be imported where the vehicles have been manufactured before 1 January 1989. An application must be made, and approval granted, in relation to each such vehicle.

Documentation and other requirements for application for licence

10. Applicants are required to provide name or company details including address and contact phone numbers. Relevant details of the vehicles to be imported are required to determine if the vehicle is eligible under the legislative requirements. Eligible persons seeking to import a previously owned vehicle are also required to provide confirmation of overseas travel and ownership and use. Copies of the application forms and access to the online application system are available from the website at: https://www.infrastructure.gov.au/vehicles/imports/application forms.

11. Importers must obtain a Vehicle Import Approval before a vehicle can be imported into Australia. Applicants are advised not to ship their vehicle to Australia without first obtaining a vehicle import approval.

12. An administrative charge of \$50 is required for the lodgement of a vehicle import approval application.

13. Payment of relevant fees must accompany the lodgement of an application for vehicle import approval. The lodgement fee is not refundable.

Conditions of licensing

14. Due to new legislation import approvals issued under the Motor Vehicle Standards Act of 1989 will expire on 9 December 2020. Approvals issued to entities holding authorities to supply new vehicles to the Australian market generally apply for the life of the vehicle model though they will expire on 9 December 2020 if issued under the Motor Vehicle Standards Act 1989. The import approvals granted for vehicles imported for test purposes normally require that such a vehicle be exported or destroyed within 12 months unless modified to legislative requirements. Approvals issued in relation to used vehicles imported by Registered Automotive Workshops also contain a condition that vehicles must be modified to meet Australian Design Rules within 12 months or must be exported or destroyed.

- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Licenses are not transferable between importers.
- 17. (a) Conditions may be applied to a Vehicle Import Approval for a vehicle that does not comply with Australian Design Rules.
- (b) Conditions may be applied to a Vehicle Import Approval.

Other procedural requirements

18. Administrative requirements of the Australian Border Force and the Australian Quarantine Inspection Service must be met before a vehicle is imported into Australia. In cases of immigrants importing their personal vehicle the requirements of the Department of Home Affairs must also be met.

19. Not applicable.

19 NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND RELATED CHEMICALS

Outline of System

1. Licences and permits are issued to control the import of specified narcotic drugs, psychotropic substances and related chemicals, including kava.

Purposes and coverage of licensing

2. This system fulfils part of Australia's obligation under three United Nations Conventions in relation to restricting the supply of controlled substances to that necessary to meet medical and scientific need and preventing diversion to the illicit drug market. The drugs covered are substances listed in Schedule 4 of the Customs (Prohibited Imports) Regulations 1956 (PI Regulations). The licensing system covers persons involved in international trade of those substances listed in Schedule 4, their derivatives, precursors and related substances. These include the drugs and chemicals required to be controlled under the *Single Convention on Narcotic Drugs, 1961*, the *Convention on Psychotropic Substances, 1971*, and Table I and Table II of the *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988*.

An exemption applies in the case of a drug that is imported by a passenger on a ship or aircraft where the drug:

(a)

- (i) is required for the medical treatment of the person or another passenger under the care of the person;
 - (ii) was prescribed by a medical practitioner for the purpose of that treatment; and
 - (iii) was supplied to the person in accordance with the prescription of the medical practitioner.

(b)

- (i) is required for the medical treatment of an animal that is being imported and is under the care of the person;
- (ii) was prescribed by a veterinarian for use in the animal for the purposes of that treatment; and
- (iii) was supplied to the person in accordance with the prescription of the veterinarian.

Incoming passengers who are over the age of 18 years are allowed to bring 2 kg of kava (*piper methysticum*) either in the root or dried form, other than a product listed or registered under the *Therapeutics Goods Act 1989*, into Australia in their accompanied baggage.

3. The system applies to importers of controlled substances from all countries.

4. The use of import licences and permits enables the Government to restrict and monitor the quantities of controlled substances imported. This is intended to prevent the over-supply and diversion of controlled substances and is one strategy adopted to address drug misuse. The

system is based on the requirements of the international treaties. The PI Regulations are not intended to restrict the quantity or volume of imports.

5. The *Customs Act 1901* and the PI Regulations govern the importation of drugs. The licensing of importers is a statutory requirement under paragraphs 50(3) (a) and (b) of the Customs Act 1901. The drugs subject to control are specified in Schedule 4 under Regulation 5 of the PI Regulations. This system cannot be abolished without legislative approval.

Procedures

- 6. I. National import limits for substances controlled by the Single Convention on Narcotic Drugs are set by an estimates system administered by the International Narcotics Control Board (INCB). The INCB publishes the estimates (import limits) for all parties to the Conventions. Allocation of limits for imports from particular countries is not applicable. Requests for exceptions and derogations from the licensing requirements must be directed to the Drug Control Section, Office of Drug Control.
- II. An annual estimate of Australia's requirements for controlled drugs is established each year based on historical records of manufacture, import, export current inventory and projected domestic consumption. Australia's estimates are published by the INCB and specific imports are only authorised where they would not be in excess of the established limit. Import licences are issued annually but in themselves do not authorise the import of any specific quantity of drug. A permit is required to import a specific drug in a specific quantity.
- III. Import permits are required for each shipment and are issued to licensed importers and the requested import quantity must not cause the total imports of the drug to exceed the Australian limit approved by the INCB. In accordance with INCB procedures Australia must establish annual estimates at the appropriate times. There is no carryover of quantity if the limit from the previous year was not reached.
- IV. Applications for licences are accepted at any time.
- V. Licence applications may take up to six weeks to process because of the stringent checks made on the personnel involved and on the security arrangements in place. Licences are issued annually. Almost all permits are issued within 20 working days of the application being submitted.
- VI. An import permit may be issued immediately following the granting of a licence. Importation could then proceed.
- VII. Licences and permits are administered by the Department of Health State licence or legislative exception must be supplied at the time of applying for a licence to import. Additional controls are imposed on some substances (for example, if the drug is not approved in Australia, quarantine restrictions, etc.) and the appropriate procedures for these controls must also be completed.
- VIII. There is no limit on the number of licences and permits to be issued. However, where relevant, the total imports cannot exceed the INCB administered estimate.
- IX. Import permits are required for all shipments of controlled substances regardless of whether an export permit is also required. In fact, for many of the controlled substances, the conventions require that the export permit can only be issued after an import permit has been sighted.
- X. As required by the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances, copies of all import and export permits are forwarded to the competent authority of the importing or exporting country.
- XI. Yes, in accordance with the *Therapeutic Goods Act 1989*.
- 7. (a) There is no minimum advance notice required for a licence. However, stringent checks of applicants for licences are undertaken in order to issue a licence. Applications for an import

permit should be made a minimum of 20 working days prior to import. Permits will only be issued to a licensed importer. Goods arriving at the port without a permit cannot be imported and retrospective permits cannot be issued.

- (b) No.
- (c) No.
- (d) Import licences and import permits are both issued by the Department of Health. When considering licence applications, State licence or legislative exception must be supplied at the time of applying for a licence to import, the company applying contacts the relevant State Authority. Other authorities may be contacted by the Department to verify application details (for example, the Australian Border Force for personnel checks of the company applying). The applicant does not need to approach these authorities.
- 8. An application may be refused for any of the following reasons:
 - The criteria are not met. These criteria require the importer to be a "fit and proper person" and maintain adequate security for storage.
 - If other permission is required but has not been obtained (for example, quarantine, State licences).

A licence or permit may be revoked if the licence holder fails to comply with the conditions of the licence or permit.

The affected person is notified in writing of any refusal or revocation. A request for review of the refusal can be made to the Australian Government Minister administering the *Therapeutic Goods Act 1989*, within 90 days after the decision first comes into the importer's notice. In the case of the applicant being dissatisfied with the Minister's finding, an application for a review of the Minister's decision can be made to the Administrative Appeals Tribunal.

Eligibility of importers to apply for licence

- 9. (a) Any person, firm or institution may apply for a licence. A licence shall not be granted unless the applicant is a fit and proper person to be granted a licence to import drugs and suitable security arrangements for the holding of drugs are in place. A licence is granted subject to conditions concerning use, sale and distribution of the substances. Import permits are only issued to licence holders. State licence or legislative exception must be supplied at the time of applying for a licence to import.
- (b) Not applicable.

Documentation and other requirements for application for licence

10. Applications for licences and permits must be submitted on either an "Application for a Licence to Import Controlled Substances" or "Application for a Permit to Import Controlled Substances" respectively.

The following information must be supplied for a licence application:

- name of the applicant (person or organisation);
- address of the premises on which the controlled substance will be held;
- nature of the business (e.g. pharmaceutical manufacture, chemical distribution, etc.);
- classes of controlled substances to be held (e.g. narcotic drugs, psychotropic substances, precursor chemicals, laboratory standards, etc.);
- details of licences held relating to the storage, manufacture or distribution of the substances;
- details of any losses and/or thefts of controlled substances;
- details of all persons who will have access to the controlled substances, including their positions and qualifications and specific background information to enable a security check;
- details of the security arrangements for the storage, distribution and handling of the substances;
- details relating to the applicant's appointment of an agent (e.g. shipping agent, customs agent);

• proposed importing activity for the period of the licence including drug names and proposed quantities.

The following information must be supplied for a permit application:

- importer's name and address;
- overseas exporter's name and address;
- product description (name, form and strength);
- number and size of the packs;
- quantity of drug;
- proposed date of import;
- mode of transport (e.g. airfreight, sea freight);
- where applicable, the name of the end user and the use of the end substance.

A separate Permit to Import is required for every shipment of a controlled substance and will not be issued unless a licence is already held. All permits must be obtained in advance of the controlled substance arriving in Australia.

11. The import permit is the required document and, for some substances, the complementary overseas export permit.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue oflicenses.

Conditions of licensing

14. Import licences are valid until the end of the calendar year. Import permits are usually valid for up to six months.

15. No. However, if a licence holder has not used the licence during the year and applies for a renewal, the applicant may need to justify retention of the licence.

16. Licences and permits are not transferable.

17. For licences, conditions apply to the keeping of records and the reporting of movements. For permits, specific conditions may be endorsed on the permit, (for example for re-export only or for veterinary use only).

Other procedural requirements

18. Importers of narcotic drugs, psychotropic substances and related chemicals for commercial supply should familiarise themselves with the requirements of the *Therapeutic Goods Act 1989* in relation to the importation of therapeutic goods for supply in Australia.

19. Not applicable.

20 OBJECTIONABLE ITEMS

Outline of System

1. Import controls exist on offensive publications and goods entering Australia. Material which is prohibited under Regulation 4A, Importation of Objectionable Goods, of the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) may not be imported without written approval of the Minister for Communications and the Arts (the Minister) or by an authorised person.

Under subregulation 4A(2A) of the PI Regulations, the Minister has appointed the Director and Deputy Director of the Classification Board as authorised persons to grant permissions to import.

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Purposes and coverage of licensing

2. Objectionable goods include: computer games; computer generated images; films; interactive games; publications and any other goods that describe, depict, express or otherwise deal with matters of sex, drug misuse or addiction, crime cruelty, violence or revolting or abhorrent phenomena in such a way that they offend against the standards of morality, decency and propriety generally accepted by reasonable adults to the extent that they should not be imported.

The goods may also be considered objectionable if the goods describe or depict in a way that is likely to cause offence to a reasonable adult, a person who is, or who appears to be, a child under 18 (whether the person is engaged in sexual activity or not). The goods may also be considered objectionable if they promote, incite or instruct in matters of crime or violence, or promote or incite the misuse of a drug specified in Schedule 4 of the PI Regulations. The goods may be considered objectionable if they advocate the doing of a terrorist act. Without limiting the above, computer games classified RC (Refused Classification) under the *Classification (Publications, Films and Computer Games) Act 1995* are also considered objectionable goods.

3. The regulations apply to the importation of goods from all countries.

4. The importation of these goods is regulated as a community protection measure. Goods included are considered to be detrimental to the well-being of the community. The PI Regulations are not intended to restrict the quantity or value of imports.

5. The control on importation of the specified goods is a statutory requirement under Regulation 4A of the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Requests for permission to import should be made in advance of arrival of the goods. Requests to the Director or Deputy Director of the Classification Board generally take up to 20 working days to process assuming the person requesting the permission has provided sufficient information to allow a decision to be made. Requests may be made if goods land and are seized by the Australian Border Force. This may happen when a person inadvertently fails to apply in advance, or does not realise the goods would be prohibited. The same processing time applies, and the Australian Border Force will delay destruction of the goods once they are notified a request for permission has been made. If the permission to import is refused or granted subject to conditions the person will be notified of the decision in writing.
- (b) No.
- (c) Permits may be issued at any period of the year.
- (d) A request for permission to import can be refused, or granted subject to conditions, on the discretion of the Minister for Communications and the Arts, or a person authorised by the Minister for Communications and the Arts. Australian Border Force is responsible for determining whether goods are "objectionable" at the border and may apply for classification if the good is a publication, film or computer game as defined in the Classification (Publications, Films and Computer Games) Act 1995.

8. Where an application is refused, or granted subject to conditions, application for review of this decision may be made to the Administrative Appeals Tribunal (AAT), and except where subsection 28(4) of the Administrative Appeals Tribunal Act 1975 applies, the applicant may request a statement of reasons for the decision. The Minister for Communications and the Arts may certify in writing that in the public interest the responsibility for permission or refusal should remain solely with the Minister for Communications and the Arts and should not be reviewable by the AAT. The certificate must include a statement of the grounds on which the certificate was issued.

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Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import.

Documentation and other requirements for application for licence

10. For permission to import applications must be made in writing to the Commonwealth Minister for Communications and the Arts or an authorised person (the Director, or Deputy Director of the Classification Board). The application should include the following information:

- importer's name and address;
- details of the goods to be imported;
- quantity and distribution (end use);
- the purposes for which the goods are to be imported;
- explanation and evidence of the extent to which the person to whom permission would be granted conducts activities of an artistic, educational, cultural or scientific nature to which the goods relate;
- evidence of the reputation of the person both in general and in relation to the activities described above; and
- explanation of the person's ability to meet any conditions that may be imposed in relation to the goods under sub-regulation 3 (i.e. custody, use, reproduction, disposal, destructions, exportation or accounting for the goods).
- any other relevant matters.

11. Proof of authorisation is required on importation.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Permits apply to one consignment only.

- 15. There is no penalty for the non-utilisation of a permission or a portion of a permission.
- 16. Licenses are not transferable between importers.

17. Conditions may be applied regarding the custody, use, reproduction, disposal, destruction or exportation of the imported goods or with respect to accounting for the goods for the purpose of ensuring that the goods are not used otherwise than for the purposes for which permission was granted.

Other procedural requirements

18. No.

19. Not applicable.

21 ORGANOCHLORINE CHEMICALS

Outline of System

1. The importation of certain organochlorine chemicals (OCs) as listed in Schedule 1 of the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 and Schedule 9 of the Customs (Prohibited Imports) Regulations 1956 is prohibited unless written permission, either from the Minister responsible for the Commonwealth Department of Agriculture or an authorised officer, is provided to the Australian Border Force at the time of importation. An authorised officer means an officer of the Department of Agriculture who is authorised in writing by the relevant Minister for the purposes of this regulation.

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Purposes and coverage of licensing

2. OCs were once commonly used in agriculture and industry, however, they have since been found to produce harmful effects on animals, people and the environment. The OCs subject to Australian import controls includes OCs controlled under domestic legislation and persistent organic pollutants that are listed under Schedule 1 of the Agricultural and Veterinary Chemicals (Administration) Regulations 1995. Schedule 1 is amended from time to time, to, inter alia, to reflect the Australian Government's ratification of decisions made by the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention).

3. For OCs subject to domestic regulation import controls apply to all countries. For the OCs listed in Schedule 1 of the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 as Stockholm Convention import controls apply to Parties to this Convention.

4. The importation of these chemicals is regulated as a community protection measure. These chemicals are considered to be generally persistent in the environment, relatively toxic and bio-accumulative. OCs listed in the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 are intended to restrict imports, unless they are for uses or purposes allowed under the Stockholm Convention (e.g. specific exemption, acceptable purpose, laboratory-scale research, reference standard or environmentally sound disposal).

5. The control on importation of the specified goods is a statutory requirement under Agricultural and Veterinary Chemicals (Administration) Regulations 1995 and Regulation 5I of the Customs (Prohibited Imports) Regulations 1956 made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Australia is a Party to the Stockholm Convention and these import controls are required of all Parties. Australia would need to withdraw from the Convention in order to abolish these import controls.

Procedures

6. Not applicable, as no organochlorine chemicals are restricted on the basis of either the quantity or value of imports.

- 7. (a) Application should be made in advance of arrival of the goods. However, if the chemicals have arrived without a permit, the Australian Border Force may hold the shipment until a decision concerning an application is made.
- (b) Permits are not normally issued immediately. Applications for permits are made to the Department of Agriculture and normally processed within five (5) business days.
- (c) No, permits may be issued at any period of the year.
- (d) Permits are issued by the Australian Department of Agriculture and are presented by the importer to the Australian Border Force at the time of importation.

8. Application for permission to import can be refused at the discretion of the Minister for Agriculture. Reasons for refusal would be explained to applicants. There is no right of appeal against the Minister's decision. However, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) All persons, firms and institutions are eligible to apply for permission to import.

Documentation and other requirements for application for licence

10. For permission to import, applications must be made in writing to the relevant Minister or authorised officer at http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/stockholm-rotterdam. The application should include the following information:

- importer's name and address; and
- details of the goods to be imported including the appropriate international codes, quantity, intended use, exporting country, date of import.

11. The written permission of the Minister or authorised officer is required to be produced on import.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Permits usually apply to one consignment only, typically valid for three months but may be extended given sufficient justification.

15. There is no penalty for the non-utilisation of a license or a portion of a license.

16. Licenses are not transferable between importers.

17. Permission granted under Agricultural and Veterinary Chemicals (Administration) Regulations 1995 and Regulation 5I of the Customs (Prohibited Imports) Regulations 1956 may specify conditions or requirements to be complied with by the holder of the permission, such as the use of the chemical (e.g. as a reference standard or for laboratory-scale experiment only). If the holder of the permission fails to comply with a condition or requirement the Minister may revoke the permission.

Other procedural requirements

18. No.

19. Not applicable.

Furtherinformationcanbefoundathttp://www.agriculture.gov.au/pagemoved?requestUrl=http://www.agriculture.gov.au/agriculture-
food/ag-vet-chemicals/stockholm-rotterdam.befoundat

22 OZONE-DEPLETING SUBSTANCES AND SYNTHETIC GREENHOUSE GASES

Outline of System

1. Australia manages its obligations under the *Montreal Protocol on Substances that Deplete the Ozone Layer* for ozone depleting substances and hyrdofluorocarbons (HFCs) and, for synthetic greenhouse gases, the *United Nations Framework Convention on Climate Change (UNFCCC)* through the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*.

The import, export and manufacture of the ozone depleting substances - chlorofluorocarbons, halons, carbon tetrachloride, methyl chloroform, bromochloromethane and methyl bromide, for non-quarantine and pre-shipment use, - is prohibited under the Montreal Protocol except where an essential or critical use exemption has been granted by the parties to the Montreal Protocol. Control measures for HFCs under the Kigali Agreement to the Montreal Protocol commence from 1 January 2019 and will phase-down the production and import of HFCs. Australia's Montreal Protocol obligations are implemented through licensing controls and quota restrictions on hydrochlorofluorocarbons (HCFC) and HFCs, and licensing of imports of methyl bromide.

Australia controls the import and manufacture of other synthetic greenhouse gases (perfluorocarbons, sulfur hexafluoride and nitrogen trifluoride) in accordance with its obligations under the Kyoto Protocol. A licence is required to import, export and manufacture synthetic greenhouse gases and to import products containing synthetic greenhouse gases.

Purposes and coverage of licensing

2. The requirements of the licensing system are:

- Controlled substances:
 - import, export or manufacture of bulk methyl bromide, with the quantity of methyl bromide permitted to be imported for non-quarantine and pre-shipment fumigations limited to the quantity approved by the Montreal Protocol;
 - import, export or manufacture of bulk HCFCs and HFCs, with import quotas set in line with Montreal Protocol phase-out obligations and Australia's domestic policy to accelerate phase-out of HCFCs and phase-down of HFCs;
 - import, export or manufacture of bulk perfluorocarbons, sulfur hexafluoride and nitrogen trifluoride, with no restrictions on quantity.
- Essential use:
 - import, export or manufacture of bulk hydrochlorofluorocarbons, chlorofluorocarbons, halons, carbon tetrachloride, methyl chloroform and bromochloromethane approved for essential use by the parties to the Montreal Protocol.
- Used substances:
 - import and export of bulk used chlorofluorocarbons, halons, carbon tetrachloride, methyl chloroform, bromochloromethane, methyl bromide, hydrochlorofluorocarbons, hydrofluorocarbons, perfluorocarbons, sulfur hexafluoride and nitrogen trifluoride.

• Equipment licences:

 precharged equipment containing synthetic greenhouse gases and refrigeration and air conditioning equipment containing HCFCs. The import of some equipment is restricted.

Effective 4 August 2017, the Australian Government increased the licence exemption threshold for low volume equipment imports to 25 kilograms of hydrofluorocarbons, perfluorocarbons, sulfur hexafluoride or nitrogen trifluoride during a calendar year.

The exemption threshold for imports of refrigeration and air conditioning equipment containing HCFCs remains at no more than five items of replacement parts for existing HCFC refrigeration and air-conditioning equipment, containing less than 10 kilograms in total of HCFC, in a single consignment. The low volume import exemption for HCFCs can only be used once in a two-year period. Note this exemption is limited to replacement parts for existing HCFC refrigeration and air conditioning equipment. All other HCFC refrigeration and air conditioning equipment is banned and cannot be brought in under this exemption.

A typical low volume importer is an individual who is importing a piece of equipment, either by itself or contained in another piece of equipment such as a motor vehicle. Importers who are eligible for this licence exemption are able to self-assess through the Ozone Licensing and Reporting System. Importers of equipment who are over the threshold continue to require an import licence under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989.

Licence conditions and reporting requirements apply in relation to all licences issued.

The import and manufacture of refrigeration and air conditioning equipment charged with a HCFC refrigerant, designed to operate only using a HCFC refrigerant or containing insulating foam manufactured with a HCFC is prohibited under the legislation, unless permitted under the equipment licence. Exemptions apply to:

- replacement parts for existing HCFC air conditioning and refrigeration equipment (to 31 December 2019);
- equipment insulated with foam manufactured with HCFC (to 31 December 2019).

In addition, certain products containing, manufactured with or designed to operate using some ozone depleting substances are prohibited from import, export or manufacture unless the Minister has approved their import. Approval would only be given where the use of a substance is essential for medical, veterinary, defence, industrial safety or public safety purposes and no practical alternative exists.

Exemptions from licencing requirements apply in limited circumstances for the import or manufacture of certain products containing synthetic greenhouse gases. Exemptions have been approved for metered dose inhalers and imported foam products.

3. The system applies to goods from all countries, with restrictions applying to trade of ozone depleting substances and HFCs with countries that are not party to the Montreal Protocol.

4. The licensing system implements Australia's legal obligations under the Montreal Protocol. As well as limits on production and consumption of ozone depleting substances and HFCs leading to eventual phase-out or phase-down, the Montreal Protocol requires the establishment of a licensing and quota system.

5. The legislation under which licences are maintained includes:

- Ozone Protection and Synthetic Greenhouse Gas Management Act 1989;
- Ozone Protection and Synthetic Greenhouse Gas (Import Levy) Act 1995;
- Ozone Protection and Synthetic Greenhouse Gas (Manufacture Levy) Act 1995;
- Ozone Protection and Synthetic Greenhouse Gas Management Regulations 1995;
- Ozone Protection and Synthetic Greenhouse Gas (Import Levy) Regulations 2004;
- Ozone Protection and Synthetic Greenhouse Gas (Manufacture Levy) Regulations 2004.

Licensing is a legislative requirement. It is an offence to import, export or manufacture a scheduled substance without a licence.

The legislation does not leave designation of products to administrative discretion. All substances that require licences are specified in a schedule to the legislation. No other substances require licensing under this legislation.

Importation of ozone depleting substances and synthetic greenhouse gases and equipment containing these substances is prohibited under provisions of the Customs Act 1901 and the PI Regulations unless a licence has been obtained or the goods are exempt from licensing requirements.

Procedures

6. The quantity of controlled ozone depleting substances and HFCs that can be imported into Australia is limited through the Montreal Protocol. These limits and the quota system are also outlined in the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*. There is no import limit on other synthetic greenhouse gases.

- I. Information on licences is published in customs notices, trade journals, on the Australian Government Department of the Environment and Energy website and in an Australian database for business. The Department of the Environment and Energy deals directly with holders of existing licences and new applicants. There are no quotas on amounts to be imported from specific countries, but imports and exports of ozone depleting substances, and HFCs when the Montreal Protocol trade provisions commence in 2033, must be from countries that are Parties to the Montreal Protocol and its relevant amendments. The legislation does not provide for any exception or derogation from licensing requirements.
- II. Controlled substances, used substances and pre-charged equipment licences are issued for two years. Fixed end dates apply to controlled substances and used substances licences, while pre-charged equipment licences are valid for two years from the date of issue. Most controlled substance licences for an ozone depleting substance and HFCs specify the amount permitted to be imported or manufactured during the licence period. Essential use licences

are issued annually. Each licence specifies the maximum amount and type of substance to be imported for the entire duration of the licence.

HCFC and HFC import quotas are based on the total annual consumption (i.e. production plus imports, minus exports) limit under the Montreal Protocol, adjusted for Australia's accelerated phase-out and phase-down policy as applicable. Individual HCFC and HFC import quotas are based on past imports. There is provision for limited HFC quota allocation for new entrants.

III. Australia has no domestic manufacture of ozone depleting substances and synthetic greenhouse gases. All HCFC and HFC quota holders are importers of substances. Any company wishing to manufacture these substances in Australia would be subject to the same licensing and quota requirements as importers.

Unused quotas are not added to those of the succeeding period as limits under the Montreal Protocol and domestic legislation are not cumulative. The names of Australian importers are available to the public on the Australian Government Department of the Environment and Energy website.

IV. Licence applications may be made at any time. The Department of the Environment and Energy will seek licence reapplications for a new licence period up to six months prior to the commencement of the licence period.

Consideration of a licence application may take up to 60 days. The *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989* provides that if after 60 days the Minister or delegate has not granted a licence or sought more information, the application is deemed to be refused, unless a formal request for additional information has been made. A request for more information provides 60 days from the date the information is received for the application to be granted or refused. If it is not granted in this period it is deemed to be refused.

- V. See IV above.
- VI. Licences can be granted at any time before or during a licence period.
- VII. The authority to grant or refuse licences lies with the Minister for the Environment and Energy. This power has been delegated to certain officers in the Australian Government Department of the Environment and Energy. Applicants need only apply to the Department of the Environment and Energy.
- VIII. There is no limit to the number of licences that can be issued under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989. The quantity of ozone depleting substances and HFCs that can be imported is limited under the Montreal Protocol and the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989. HCFC and HFC imports are managed through a quota system, based on past imports. There is provision for HFC quota allocation for new entrants.
- IX. Not applicable.
- X. Not applicable.
- XI. Not applicable.
- 7. (a) A licence for import of pre-charged equipment may be applied for at any time, prior to the goods being imported. Consideration will be given to granting a licence after goods have arrived. Applicants are discouraged from organising an import until a licence has been granted. Under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989, licence applications must be assessed within 60 days of receipt.
- (b) The application must be assessed within the terms of the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*. There is no minimum waiting period f o r assessment once all information has been provided and the application fee paid.

- (c) Controlled substances licences can be granted at any time during the licence period. If granted, the licence will expire at the end of the current licence period, regardless of when the licence was actually granted. Ozone Depleting Substance/Synthetic Greenhouse Gas Equipment, licences are valid for two years from the date of issue.
- (d) The Department of the Environment and Energy considers licence applications. No other agencies are involved.

8. A licence may be refused if the applicant does not meet ordinary criteria. Where applications are refused, applicants will be given the reasons for such refusal on request. An applicant may apply to the Administrative Appeals Tribunal for a review of the decision not to approve a licence. Alternatively, an appeal may be made on the decision-making process itself under the Administrative Decisions (Judicial Review) Act 1977.

Eligibility of importers to apply for licence

- 9.(a) Noting the quota restrictions for HCFC and HFC imports, all persons, firms and institutions are eligible to apply for licences.
- (b) All persons, firms and institutions are eligible to apply for licences.

Documentation and other requirements for application for licence

10. Controlled Substance, Essential Use, Used Substance and Pre-charged Equipment application forms are available on the Department of Environment and Energy website at: http://www.environment.gov.au/protection/ozone/licences.

11. Upon importation, an importer must present standard customs documentation along with a valid licence issued under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989.

12. Licence application fees are charged. Fees are: Controlled substances - \$15,000; Essential Use - \$3,000; Used Substance - \$15,000; and Pre-charged Equipment - \$3,000.

In addition, licence holders are required to pay a 6-monthly activity fee: HCFC - \$3,000 per ODP (Ozone Depleting Potential) metric tonne; Methyl Bromide - \$135 per metric tonne; synthetic greenhouse gases - \$165 per metric tonne.

13. There is no deposit or advance payment requirement associated with the issue of licences.

Conditions of licensing

- 14. Licences are valid for the licence period and cannot be extended.
- 15. There is no penalty for the non-utilisation of a licence or a portion of a licence.

16. Yes. Transferee must be a fit and proper person to be a licence holder. A joint application by the transferor and transferee is made to the Department of the Environment and Energy.

17. Licensees are not permitted to trade in ozone depleting substances with non-parties to the Montreal Protocol. General conditions of the licence are that the licensee must have arrangements in place to manage their product at its end of life, generally through a product stewardship scheme; and must provide 6 monthly activity reports and pay the appropriate import levy, as per the Ozone Protection and Synthetic Greenhouse Gas Act 1989.

Conditions may also apply to the purpose to which the imported substance is to be applied if its import has been approved for a specific purpose through the Montreal Protocol.

Other procedural requirements

18. No.

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19. Not applicable.

23 PLASTIC EXPLOSIVES

Outline of System

1. The importation of plastic explosives is generally prohibited under provisions of the *Customs Act 1901*, the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) and the *Criminal Code Act 1995* (Cth) (Criminal Code). Importation is lawful if the Minister for Home Affairs (the Minister) has issued a permit under the PI Regulations and, if applicable, an authorisation is provided under the provisions of the Criminal Code. The Criminal Code regime fulfils part of Australia's obligation under the *United Nations Convention on the Marking of Plastic Explosives for the Purpose of Detection* (Montreal, 1991) (the Convention).

Purposes and coverage of licensing

2. The goods covered are plastic explosives. Different requirements apply depending on whether plastic explosives are "marked" with a chemical marker specified in the Criminal Code.

3. The Department of Home Affairs and state and territory import licensing and permissions systems apply to importers of plastic explosives from all countries, regardless of whether the explosives are marked.

The Criminal Code requirements apply to both imported and domestically produced explosive products from all countries. That authorisation scheme applies to importers of plastic explosives that are not marked.

4. The PI Regulations are not intended to restrict the quantity or volume of imports. There are no restrictions in relation to the quantity or value of imports of unmarked plastic explosives under the Criminal Code regime. However, in exercising power to grant an authorisation, the Minister for Home Affairs may have regard to whether the import of unmarked plastic explosives is reasonable.

5. The control of plastic explosives is a statutory requirement under Regulation 4AA of the PI Regulations made under the Customs Act 1901. The control cannot be abolished without legislative approval. The provisions requiring Authorisation to be obtained for certain dealings with unmarked plastic explosives under the Criminal Code cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7. (a) No specific timeframe. However, it is recommended that the application forms are completed and submitted at least six weeks before the goods' expected arrival in Australia.

In addition, the importer must provide the State or Territory Permit or Licence to import plastic explosives on the Application for Permission to import plastic explosives form and on the Manufacturers Certificate, relevant to the Home Affairs and Criminal Code regimes respectively. In the case of unmarked plastic explosives, an Application for Authorisation to import unmarked plastic explosives should be lodged with the Department of Home Affairs before seeking permission to import.

(b) A permit to import would not normally be granted immediately as some conditions must be fulfilled. Checking of applicants' suitability to hold a permit generally takes some time and therefore permits cannot generally be issued immediately upon request.

An Application for an Authorisation under the Criminal Code regime must be submitted to the Department of Home Affairs for consideration and, if the Application is approved, an instrument of authorisation is executed and provided to the applicant. The process may take approximately two to three weeks.

(c) No.

(d) Granting permission for the importation of plastic explosives involves state and territory licensing authorities, the Department of Home Affairs. Authorisations and Permissions to import unmarked plastic explosives and Permissions to import marked plastic explosives are granted by the Minister or an authorised officer.

8. Unless otherwise stated, the regulations allow the Minister to consider whatever he or she believes necessary in forming a view as to whether or not to grant a permit. An import permit issued by the Minister or an authorized person may be revoked if the permit holder engages in conduct that contravenes a condition or requirement of the permission.

An authorisation to import unmarked plastic explosives may be refused by the Minister if he or she considers that the proposed importation is unreasonable and/or considers that the authorisation ought not be granted having regard to such matters as he or she considers relevant. An application may be made to the Administrative Appeals Tribunal for review of the Minister's decision to refuse to grant an Authorisation or the Minister's decision to specify a condition or restriction in an Authorisation made under section 72.18(1) (authorisation for research), section 72.19(1) (authorisation for defence and police purposes), section 72.20(1) (authorisation for use of existing stocks) or section 72.21(2) (authorisation for manufacturers).

The Minister or his or her authorised officer would be required to give reasons for refusing to grant an Authorisation. If the Minister's decision is affected by jurisdictional error or error of law, it is susceptible to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) Any person, firm or institution may apply for a permit. A permit shall not be granted unless the applicant is a fit and proper person to be granted a permit to import plastic explosives. Individuals, institutions, or corporations are eligible to apply for an authorisation to import unmarked plastic explosives.

Documentation and other requirements for application for licence

10. In order to import unmarked plastic explosives importers will need to complete:

- an application for authorisation to either manufacture, possess, traffic in, import or export unmarked plastic explosives;
- an application for permission to import unmarked plastic explosives; and
- a manufacturers certificate.

In order to import marked plastic explosives importers will need to complete:

- an application for permission to import marked plastic explosives, and
- a manufacturers certificate.

A state or territory licence or permit must be obtained before the Minister can authorise the importation of plastic explosives and before the plastic explosives arrive in Australia. If the permission to import plastic explosives (and authorisation if the plastic explosives are unmarked) is obtained from the Minister, a permit number will be issued. This permit number must be presented to the Department of Home Affairs at the time of lodging an import declaration.

11. A state or territory import licence or permit is required on actual importation of marked or unmarked plastic explosives. In addition to the state or territory licence or permit, additional documentation must be completed as specified in response to question (10) above.

12. A state or territory import licence or permit is required on actual importation of marked or unmarked plastic explosives. In addition to the state or territory licence or permit, additional documentation must be completed as specified in response to question (10) above.

13. No deposit or advance payment is required. No deposit or advance payment is associated with the issue of permissions or authorisations by the Minister.

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Conditions of licensing

14. The Minister may issue an authorisation for the importation of unmarked explosives for defence or police purposes until 25 August 2022. Existing authorisations cannot be extended. If an existing user wishes to engage in an activity other than one which is covered by the terms of an existing authorisation, a new application must be made.

15. There is no penalty for non-utilisation of a permit. However, if a permit holder has not used the permit during the year and applies for a renewal, the applicant may need to justify retention of the permit. There is no penalty for non-utilisation of an authorisation issued by the Minister.

16. Permits and authorisations issued by the Department of Home Affairs are not transferable and apply only to those applicants to whom the authorisation was initially granted.

- 17. (a) Not applicable.
- (b) The importation of unmarked plastic explosives (which are not subject to quantitative restriction) may be subject to such conditions and restrictions as the Minister may specify in the authorisation. Such conditions may include a requirement that future stocks of unmarked plastic explosives be purchased only from a specified source and/or that the applicant inform the Department of Home Affairs of any additional consignments of unmarked plastic explosives acquired following the grant of an Authorisation.

Other procedural requirements

18. No.

19. Not applicable.

Weblinks to the relevant Acts and Regulations are as follows:

- Criminal Code Act 1995: <u>https://www.comlaw.gov.au/Details/C2015C00601</u>
- Customs Act 1901: <u>https://www.comlaw.gov.au/Details/C2016C00066</u>
- Customs (Prohibited Imports) Regulations 1956: https://www.comlaw.gov.au/Details/F2016C00106
- United Nations Convention on the Marking of Plastic Explosives for the Purpose of Detection (Montreal, 1991): https://treaties.un.org/Pages/DB.aspx?path=DB/studies/page2_en.xml

24 RADIOACTIVE SUBSTANCES

Outline of System

1. The importation of radioactive substances and goods containing radioactive substances is prohibited under the provisions of the *Customs Act 1901* and Customs (Prohibited Imports) Regulations 1956 (PI Regulations) unless the permission in writing is granted by the Australian Minister for Health, the CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) appointed in writing by the Minister, or an Australian Public Service employee assisting the CEO appointed in writing by the Minister as an authorised officer, and presented to the Australian Border Force at the time of importation. In order for a permit to be considered, the entity taking possession of the sources, including the recipient/s, must be hold a valid and current radiation licence to possess, sell or store radioactive substance, where required. The Radiation Licence is obtained from the relevant Commonwealth, state or territory radiation regulatory control authority where required.

Purposes and coverage of licensing

2. The goods covered include any radioactive material or substance including radium, any radioactive isotope or any article containing any radioactive material or substance.

3. The PI Regulations apply to the importation of radioactive substances from all countries.

4. The importation of radioactive substances is regulated as a community protection measure and to comply with Australia's international obligations under the *Basel Convention on the Control of trans-boundary Movements of Hazardous Wastes*. The PI Regulations are not intended to restrict the quantity or volume of imports.

5. The control on importation of the specified goods is a statutory requirement under Regulation 4R of the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

6. Not applicable.

- 7. (a) Application should be made in advance of the arrival of the goods.
- (b) Permits to import are granted when it is established that the recipient/s taking possession of the radioactive substances have obtained the required radiation Licence, where required, from the relevant Commonwealth, State or Territory radiation control authority. For the import of radioactive substances, the relevant Commonwealth, State or Territory radiation control authority is advised of the application for permission to import.
- (c) Permits may be issued at any period of the year.
- (d) A permit is issued by the Minister for Health, the CEO of ARPANSA or an Australian Public Service employee assisting the CEO appointed in writing by the Minister as an authorised officer. Applications to import radioactive materials or articles containing radioactive materials must be made to ARPANSA on Form ARPANSA 20, "Application for Customs Prohibited Import Release for Medical Radioisotopes", or on REG-PER-FORM-310A, "Application for Permission to Import Non-Medical Radioactive Substances" or on REG-PER-FORM-310B, "Application for permission to import non-medical radioactive substances - Twelve month permit". These forms, and instructions for completing the forms, are available on the ARPANSA website (<u>https://www.arpansa.gov.au/regulation-and-licensing/licensing/importexport-permits</u>).

Before submitting an application for permission to import, the recipient/s taking possession of the radioactive substance must hold a valid Radioactive Substances Licence, where required, from the relevant Commonwealth, State or Territory radiation control authority. The licence number and licence details must be stated on the application form.

8. Application for permission to import can be refused on the discretion of the Minister for Health. There is no right of appeal against the Minister's decision. However, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act* 1977.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import

Documentation and other requirements for application for licence

10. For permission to import, applications must be made in writing to ARPANSA on the appropriate form available on the ARPANSA website: <u>https://www.arpansa.gov.au/</u>. The application should include the following information on the permit application form:

• Applicant's name and address;

- end users name and address;
- storage premises details;
- details of the radioactive substance;
- details of the goods to be imported; and
- details of the Radioactive Substance Licence.

Application forms are available on the ARPANSA Web site (<u>https://www.arpansa.gov.au/regulation-and-licensing/licensing/import-export-permits/non-medical-import-permits</u>).

11. The written permission from the Minister of Health, or an authorised officer, an approved signed import permit, is required to be produced on import.

12. ARPANSA has an administrative charge for the granting of a single shipment permit, and for the granting of a Twelve-Month Permit as per the charge fee structure on the ARPANSA website: https://www.arpansa.gov.au/regulation-and-licensing/l

13. There is no deposit or advance payment requirement associated with the issue of permits.

Conditions of licensing

14. Permits for the importation of medical or non-medical radioisotopes may apply to one consignment only, or may apply for a number of importations for a specified twelve-month period (Twelve Month Permit). Twelve-Month Permits are issued for the importation of radiopharmaceutical drugs registered on the Australian Register for Therapeutic Goods (ARTG) and for low hazard radioactive materials. The holder of a Twelve-Month Permit is required to ensure that they and the recipient/s of the radioactive substances with the relevant radiation regulatory control authority where applicable. A single shipment permit is valid for six (6) months.

15. There is no penalty for the non-utilisation of a permit or a portion of a permit.

16. Permits are not transferable between importers or permit applicants.

17.

- (a) Not applicable.
- (b) Permission granted under Regulation 4R of the PI Regulations may specify conditions or requirements to be complied with by the holder of the permission.

All forms and requirements for import of radioactive substances can be found on the ARPANSA website at <u>https://www.arpansa.gov.au/regulation-and-licensing/licensing/import-export-permits</u>.

Other procedural requirements

18. No.

19. Not applicable.

25 SECURITY SENSITIVE AMMONIUM NITRATE

Outline of System

1. The importation of security sensitive ammonium nitrate (SSAN) is prohibited under the provisions of the <u>*Customs Act 1901*</u> and <u>*Customs (Prohibited Imports)* Regulations 1956 (PI Regulations)</u> unless:

- (a) Permission has been granted for the importation by the state/territory authority where the goods will be located immediately after arrival and that is presented to Home Affairs at the time of importation; or
- (b) the state/territory does not require permission to import.

A licence is required to import SSAN into the following States and Territories: Queensland, New South Wales, Australian Capital Territory, Victoria, Tasmania, Western Australia and South Australia.

Purposes and coverage of licensing

2. The goods covered include security sensitive ammonium nitrate (SSAN). SSAN is ammonium nitrate, a mixture or emulsion made up of more than 45% ammonium nitrate, but not ammonium nitrate in solution.

3. The PI Regulations apply to the importation of goods from all countries.

4. The importation of SSAN is regulated as a community protection measure. SSAN is a chemical of security concern and is regulated by the states/territories under dangerous goods legislation. The PI Regulations are not intended to restrict the quantity or volume of imports.

5. The control on importation of the specified goods is a statutory requirement under Regulation 4X of the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Applications for import licences should be made at least 7 working days in advance of the importation. Licences are granted by state/territory authorities. Where other licences for SSAN are held (e.g. export) a shorter timeframe may apply.
- (b) Licences cannot be issued immediately as the licence holders need to satisfy a number of conditions under the relevant state/territory legislation that the licence is granted under.
- (c) Licences may be issued at any period of the year.
- (d) The licences are specific to each state/territory within Australia. This means that to import SSAN into more than one jurisdiction, multiple authorities need to be approached. The licensing authority in each state/territory consults other government agencies in the licensing process.

8. Licence applicants must satisfy the requirements of the legislation in the relevant jurisdiction. Appeal provisions are managed by those jurisdictions.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import although they must satisfy the requirements of the legislation in the jurisdiction where they are applying for the licence.

Documentation and other requirements for application for licence

10. Applications for licences must be made to the relevant State/Territory authority on the approved form for that state/territory and include all relevant particulars. The documents required to be submitted vary depending on the jurisdiction and whether the applicant holds other licences for SSAN or other dangerous goods.

The relevant agencies are:

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State/Territory	Agency
Queensland	Department of Mines and Energy
New South Wales	WorkCover Authority NSW
25.1. Australian CapitalTerritory	WorkSafe ACT
25.2. Victoria	WorkSafe Victoria
25.3. Tasmania	WorkPlace Standards Tasmania
25.4. Western Australia	Department of Mines and Petroleum
25.5. South Australia	SafeWork South Australia

11. Where permission is required in the state/territory of importation, the permission from the relevant State/territory authority must be produced to the Australian Border Force on import.

12. Licensing fees are charged by the state/territory licensing authorities and vary depending on the type of licence sought.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Licensing periods vary in each jurisdiction. They range from 1 year to 5 years.

15. There is no penalty for the non-utilisation of a license or a portion of a license.

16. Licenses are not transferable between importers.

17. Licences may impose conditions to be complied with.

Other procedural requirements

18. Not applicable.

19. Not applicable.

26 TABLET PRESSES

Outline of System

1. The importation of tablet presses is prohibited under provisions of the <u>*Customs Act 1901*</u> and the <u>*Customs (Prohibited Imports) Regulations 1956*</u> (PI Regulations) unless the permission of the Minister for Home Affairs, or an authorised person, has been obtained.

Purposes and coverage of licensing

2. Tablet presses are defined as manual, semi-automatic or fully automatic equipment which can be used for the compaction or moulding of powdered or granular solids, or semi-solid material to produce coherent solid tablets.

3. The system applies to the importation of goods originating from all countries.

4. The PI Regulations are not intended to restrict the quantity or volume of imports. A permission can specify conditions or requirements including times for compliance and the number of tablet presses allowed to be imported. The Minister or an authorised person has the power to revoke permission where the holder does not comply with a condition or requirement. The manufacture and distribution of amphetamine type stimulants is a serious problem in Australia and preventing the importation of tablet presses for use in illicit markets is an important way of reducing domestic production.

5. The control on the specified goods is a statutory requirement under Regulation 4G of the <u>PI</u> <u>Regulations</u> made under the <u>Customs Act 1901</u>. The control cannot be abolished without legislative approval.

Procedures

6. Not applicable.

7. Where there is no quantitative limit on importation of a product or on imports from a particular country:

- (a) Application should be made in advance of arrival of the goods.
- (b) for permission to import can be processed immediately provided all information is available and the application is considered to be urgent.
- (c) Permits may be issued at any period of the year.
- (d) Granting permission for the importation of tablet presses involves state and territory authorities and the Department of Home Affairs. Advice received from the relevant state or territory police force and the Australian Criminal Intelligence Commission (ACIC) plays a major role in the decision-making process. The Department of Home Affairs takes the responsibility to contact state and territory authorities as part of the decision-making process.

8. Application for permission to import can be refused at the discretion of the relevant Minister. Reasons for refusal are given to applicants. Applicants refused permission to import may appeal the decision-making process under the *Administrative Decisions (Judicial Review) Act 1977.*

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply.

Documentation and other requirements for application for licence

10. Applications must be made in writing to the Minister for Home Affairs or an authorised person. The application should include supporting documentation to possess the goods and/or any relevant end user evidential documentation. The application form can be found at: https://www.abf.gov.au/form-listing/forms/b712.pdf.

11. The original permission from the Minister or authorised person is required upon importation.

- 12. There is no licensing fee.
- 13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

- 14. The Minister may specify a time period for the validity of the permission.
- 15. There is no penalty for the non-utilisation of a license or a portion of a licence.
- 16. Permits/licenses are not transferable between importers.
- 17. Conditions may be imposed on the permission and quantities are specified.

Other procedural requirements

18. No.

19. Not applicable.

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27 THERAPEUTIC SUBSTANCES AND GOODS

Outline of System

1. Importation into Australia of therapeutic goods for human use is controlled under the *Therapeutic Goods Act 1989*, and its Regulations, and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations).

Under the *Therapeutic Goods Act 1989*, therapeutic goods may not be imported into Australia unless they are registered, listed or included in the Australian Register of Therapeutic Goods (ARTG) or specifically exempt from this requirement. One exemption is for personal importation of therapeutic goods. Under Schedule 5 of the Therapeutic Goods Regulations 1990, an individual may import a therapeutic good into Australia on their person, or arrange from within Australia for a therapeutic good to be sent to them from an overseas supplier, subject to the following:

- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person;
- the quantity imported may not exceed three months' supply per importation and the total quantity imported per year cannot exceed 15 months' supply at the manufacturer's recommended maximum dosage;
- substances, which are a prohibited import under the PI Regulations, may not be imported without an import permit;
- products which are injections containing material of human or animal origin (except insulin) may not be imported as personal imports, without permission from the Therapeutic Goods Administration;
- products which are "biologicals", as defined under the Therapeutic Goods Act 1989, may not be imported as personal imports, without permission from the Therapeutic Goods Administration; and
- in order to import any product which is a prescription medicine (substances in Schedules 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons), the importer must have a prescription issued by a medical practitioner registered in an Australian State or Territory (Note: medicines carried by a passenger on a plane or ship are an exception to this requirement, however, an import licence is still required in the case of medicines in Schedule 4 of the PI Regulations if the passenger does not have a prescription).

Importation of certain substances is prohibited under regulations 5A, 5G and 5H of the PI Regulations except with the permission of the Secretary of the Australian Department of Health. These substances include antibiotics, certain hormones (included in Schedules 7A of the PI Regulations) and other substances, including anabolic or androgenic substances (included in Schedule 8 of the PI Regulations). Substances of human or animal origin are not prohibited imports *per se*.

Importation of narcotic drugs, psychotropic substances and related chemicals, including kava, is also controlled under the PI Regulations. Those controls are described separately in this document, in the section titled "Narcotic Drugs, Psychotropic Substances and Related Chemicals".

Purposes and coverage of licensing

2. Import permits are issued under the PI Regulations both for goods approved for marketing in Australia and for "unapproved" goods where supply is considered appropriate (e.g. in the context of clinical trials or special patient access). The therapeutic substances/goods covered are:

- Substances named in regulation 5A (1) of the PI Regulations. Currently, only antibiotic substances are so specified. Exemption applies in the case of:
 - antibiotics carried by a passenger on a ship or aircraft where the antibiotics are for the sole use of the passenger or the passenger's relative, and the amount does not exceed 3 months' supply of the substance at the maximum dosage recommended by the manufacturer of the substance; or
 - antibiotics required for the use of an animal that is being imported and is under the care of a passenger on the same ship or aircraft and the amount does not exceed 3 months' supply of the substance at the maximum dosage recommended by the manufacturer of the substance; or

- antibiotics imported by a member of a group of persons visiting Australia to participate in a national or international sporting event, and for use in the treatment of a member or members of that group or an animal that is being imported and is under the care of the group;
- Goods to which regulation 5G of the PI Regulations refer, that is, goods, which are, listed in Schedule 7A to the Regulations. Schedule 7A currently lists therapeutic goods which are mostly, hormones. Exemption applies where:
 - the substance is required for the medical treatment of a person who is a passenger on a ship or aircraft; and
 - \circ $\,$ the substance is imported into Australia on the ship or aircraft; and
 - \circ the substance was prescribed by a medical practitioner for that treatment; and
 - the amount of the substance imported does not exceed the amount of the substance prescribed by the medical practitioner for the person receiving the treatment.

However, the above exemption does not apply if the goods are required for the medical treatment of a person who is an athlete within the meaning of section 4 of the *Australian Sports Anti-Doping Authority Act 2006*; or a person who has come to Australia for purposes relating to the performance of a competitor or the management of a competitor or a competitor's interest.

- Goods to which Regulation 5H of the PI Regulations refers, that is, goods listed in Schedule 8 to the Regulations. Schedule 8 includes anabolic or androgenic substances.
- 3. The regulation applies to the importation of therapeutic goods from all countries.

4. The controls under the *Therapeutic Goods Act 1989* safeguard public health in Australia through regulation of the quality, safety and efficacy or performance of therapeutic goods intended for supply in Australia.

The controls under the PI Regulations are intended to restrict entry to Australia of substances that may be the subject of abuse in one form or another, or pose a risk to public health such that they should not be accessible to the general public via personal import arrangements. The importation of antibiotics is regulated as a public health measure. It also allows information on the distribution and consumption of antibiotics in Australia to be obtained. Goods listed in Schedules 7A and 8 to the PI Regulations are those known to be associated with particular hazards or concerns, which warrant restriction or prohibition of their use. The PI Regulations are not intended to restrict the quantity or volume of imports.

5. The controls on importation of therapeutic goods are statutory requirements under the *Therapeutic Goods Act 1989*, and associated regulations, and under the *Customs Act 1901*, and associated PI Regulations. The system cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Application for importation should be made in advance of the arrival of the goods. In certain circumstances, import permission can be given for goods which have inadvertently arrived at the point of entry.
- (b) Permits may be issued immediately if a genuine emergency exists.
- (c) Permits may be issued at any period of the year.
- (d) Applications for import permits under regulations 5A, 5G and 5H of the PI Regulations are processed and issued within the Department of Health.

8. If an import permit under regulations 5A, 5G or 5H of the PI Regulations is refused, the applicant is notified in writing of the reasons for refusal. A request for review of the refusal can be made to the Australian Government Minister who administers the *Therapeutic Goods Act* 1989, within 90 days after the decision first comes into the importer's notice. In the case of the applicant being dissatisfied with the Minister's finding, an application for a review of the Minister's decision

can be made to the Administrative Appeals Tribunal. In addition, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) All persons, firms and institutions are eligible to apply for permission to import provided they are domiciled in Australia. They must also comply with any State/Territory legislation relating to manufacture and wholesale.

Documentation and other requirements for application for licence

10. For permission to import antibiotics under Regulation 5A (1) of the PI Regulations, applications should be made in writing, including the following information:

- importer's name and address;
- name of the manufacturer and location of the manufacture;
- details of the goods to be imported (whether raw material or formulated product);
- quantity and distribution (end-use);
- State/Territory Schedule 4 (prescription only medicine) licence number.

For permission to import goods specified in Schedule 8 (Regulation 5H of the PI Regulations) the written application must include:

- importer's name and address;
- full details of the product proposed for import;
- supervising doctor's prescription, if applicable;
- State/Territory Schedule 4 (prescription only medicine) licence number (if applicable);
- depending on the nature of the goods and the intended purposes, further documentation or evidence may be required.

11. Import authorisation is usually issued in the form of a permit, but may be by letter of authority.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue oflicences.

Conditions of licensing

14. Import permits may apply to one consignment only, or remain valid for successive consignments within a stated period (usually one year).

15. There is no penalty for the non-utilisation of a permit or a portion of a permit.

16. Permits are not transferable between importers.

17. Conditions are not usually related to the quantity imported for substances named in Regulation 5A (1) of the PI Regulations. Permits issued for substances in Schedules 7A and Schedule 8 of the PI Regulations are subject to individual quantitative restrictions. However, there is no annual quota or annual quantitative restrictions applicable to these goods required under the legislation or under an international agreement.

The quantitative restriction applies to individual importers as a condition of the import permit and is based on established need and enduse.

Import permits may also cite such matters as:

- compliance with other State, Territory and Commonwealth laws;
- the subsequent use of the therapeutic good;
- the custody, use, disposal or distribution of the imported goods;

- the keeping of records relating to the imported goods; and/or
- a time restriction within which the importation must occur.

Other procedural requirements

18. Importers of therapeutic goods for commercial supply should familiarise themselves with the requirements of the *Therapeutic Goods Act 1989* in relation to the importation of therapeutic goods for supply in Australia. Further information is available at http://www.tga.gov.au/.

19. Not applicable.

28 UNMANUFACTURED TOBACCO LEAF

Outline of System

1. The importation of unmanufactured tobacco leaf is prohibited under provisions of the *Customs Act 1901* (Customs Act) and the Customs (Prohibited Imports) Regulations 1956 (PI Regulations) unless the permission of the Commissioner of Taxation, or an authorised person, has been obtained. Permission from the Commissioner requires an Excise licence to manufacture tobacco or a licence to deal in tobacco products, granted under the *Excise Act 1901* (Excise Act). In addition, the site where imported tobacco leaf is to be dealt with must be licensed under the Customs Act.

Purposes and coverage of licensing

2. The goods covered include tobacco that is not stemmed or stripped and includes whole tobacco plants or leaves in the natural state, or as cured or fermented leaves. Licensed tobacco manufacturers and dealers who also hold a permission to import unmanufactured tobacco leaf (permission) are able to import these goods as an input to manufacture or more generally deal in tobacco seed, plant or leaf.

3. The system applies to unmanufactured tobacco leaf originating from all countries.

4. The PI Regulations are not intended to restrict the quantity or volume of imports. The importation of unmanufactured tobacco leaf is regulated to limit access to those licensed as manufacturers or dealers and therefore reduce illicit production.

5. The control on the specified goods is a statutory requirement under Regulation 4D of the PI Regulations made under the *Customs Act 1901*. The control cannot be abolished without legislative approval.

An Excise licence for tobacco is a legislative requirement under Sections 25 (Manufacturers) and 33 (Dealers) of the Excise Act. There is no administrative discretion – manufacturers or dealers in tobacco leaf must be licensed under the Excise Act. The control cannot be abolished without legislative approval.

A Customs warehouse licence is issued under Section 79 of the *Customs Act 1901*. Anyone intending to use imported goods in excise manufacture must enter those goods for warehousing in a Customs licensed warehouse. Those goods must then be administratively transferred to an entity holding a tobacco manufacture or dealers licence issued by the Australian Tax Office (ATO) under the Excise Act. There is no administrative discretion – imported tobacco leaf must be entered for warehousing. The control cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) The ATO standard for issuing manufacturer licences, dealers' licences or permissions is 28 days from receipt of all required information. The same standard is applied to the issuing of ATO issued warehouse licences under S79 of the Customs Act.
- (b) No.

- (c) No.
- (d) Yes, the application for an Excise licence and a permission is considered in its entirety by the ATO. From 1 July 2010, the ATO took over the administration of excise equivalent goods (EEGs) under delegation from the Department of Home Affairs (Home Affairs). As imported tobacco leaf can only be imported into Australia by entering it into a warehouse licensed under the Customs Act, the ATO has responsibility for licensing any warehouse that would store this product.

8. Failure to meet the ordinary criteria, as described in sections 39, 39A, 39B & 39C of the Excise Act, are grounds for refusing to grant a manufacturer or dealer licence. These grounds include where the applicant is not deemed fit and proper, the applicant does not have the skills and experience to carry out the activity, or the applicant does not have a market for the goods. When a licence is refused, the applicant is provided with reasons for the decision in writing. Applicants have a right to object under section 39Q of the Excise Act.

Sections 80 and 81 of the Customs Act are the key requirements that are considered when assessing an application for a Customs warehouse licence. These grounds are similar to those listed in the Excise Act. When a licence is refused, the applicant is provided with reasons for the decision in writing. Applicants have a right to object to the Administrative Appeals Tribunal under section 273GA(1)(b) of the Customs Act.

Regulation 4D of the PI Regulations states that consideration must be given to the applicant's compliance with the Excise Act and any other relevant matters when assessing a permission to import unmanufactured tobacco leaf. The same regulation allows a person who is dissatisfied with a decision to object to it in the manner set out in Part IVC of the *Taxation Administration Act 1953*.

Eligibility of importers to apply for licence

9. Yes. As long as the person or business has a site to be licensed in Australia they can apply. Excise and Customs licences are linked to sites as well as the individual or company applying. Each site operated by a single entity must be licensed separately so that the licence application can be assessed in terms of appropriateness of site security, plant and equipment, and stock recording for each site.

In relation to the permission, the entity must hold either an Excise manufacturer or dealer licence, and the site where imported tobacco is to be dealt with must be licensed under the *Customs Act 1901*.

Documentation and other requirements for application for licence

10. An application for a Licence to Manufacture Tobacco must be made in writing to the ATO. Application forms can be found at: <u>https://www.ato.gov.au/Forms/Licence-to-manufacture-tobacco/</u>

To obtain an Application to deal in tobacco seed, plant or leaf the applicant will need to <u>contact</u> the ATO.

The application for a warehouse licence issued under S79 of the Customs Act can be found at: https://www.ato.gov.au/business/excise-and-excise-equivalent-goods/excise-equivalent-goods/excise-equivalent-goods- (imports)/customs-warehouse-licences/

If an applicant is applying for the first time, that applicant will be required to complete a Consent to a Criminal Record History Check and a Declaration of criminal history.

Applicants are also required to supply the following information:

- Name, address, ABN and other contact details;
- Details of the premises where the activity will occur including certified copies of the floor plan of the proposed licence site;
- Supplier's name and address;
- Quantity of product.

Finally, during the review process the applicant may be required to send additional documents in support of their claims - for example, a business plan, evidence of a market, details of security arrangements or insurance policy details.

There is no specified application form for the import permission, although a written application must be lodged providing the Commissioner with any information he reasonable requires to make his decision.

11. The original permission from the Commissioner or authorised person must be produced upon importation in addition to the normal importation documentation required by Home Affairs.

12. There are no fees associated with the Excise licences or the permission. There are fees associated with the customs warehouse licence. The initial application fee is A\$3000 and the grant charge is A\$4,000. There is an annual renewal fee of A\$4000.

13. No.

Conditions of licensing

14. A licence to manufacture or deal in tobacco is valid for 3 years and must be renewed before the end of the 3-year period. The validity of a licence can be extended if it is approved for renewal by the ATO. The associated permission is valid for the same period as the licence although, rather than being renewed, it must be re-issued. This is an administrative requirement only.

In contrast, a warehouse licence is valid for 1 year only and must be renewed annually. The validity of a licence can be extended if it is approved for renewal by ATO staff operating under Customs delegation.

15. No.

16. Excise manufacturer, dealer or Customs warehouse licences are not transferable. Although the ATO licenses the site, the licence cannot be transferred and any change in ownership would require a new licence application. The permission also is not transferable.

17. (a) Not applicable.

(b) Section 39D of the Excise Act and section 82 of the *Customs Act 1901* allow the ATO to apply conditions to a licence to protect the revenue or to facilitate compliance with the relevant Acts. There are no limitations on the conditions that can be applied on a permission under Regulation of the Customs PI Regulations.

Other procedural requirements

18. No.

19. Not applicable.

Links to legislation:

- Excise Act 1901: www.comlaw.gov.au/Details/C2015C00361
- Customs Act 1901: https://www.comlaw.gov.au/Details/C2016C00066
- Customs (Prohibited Imports) Regulations 1956: https://www.comlaw.gov.au/Details/F2016C00106
- Taxation Administration Act 1953: https://www.comlaw.gov.au/Details/C2016C00009

29 VIABLE MATERIAL DERIVED FROM HUMAN EMBRYO CLONES

Outline of System

1. The *Prohibition of Human Cloning for Reproduction Act 2002* (section 23C) required the Minister who administers the *Customs Act 1901* to make regulations "permitting, subject to appropriate

conditions or restrictions, the import and export of human embryonic stem cell lines which have been derived from human embryo clones using practices consistent with Australian legislation".

The relevant regulation is regulation 5L of the Customs (Prohibited Imports) Regulations 1956. The regulations prohibit the import of viable material derived from human embryo clones unless the Minister administering the Prohibition of Human Cloning for Reproduction Act 2002, or an authorised person has granted permission in writing and the permission is produced at or before the time of import.

Although the first embryonic stem cell lines from human embryo clones were reported in May 2013, a request for permission to import such material has not yet been made. Details of the permit system will be developed as required and prospective importers can contact the National Health and Medical Research Council (NHMRC) for information.

Purposes and coverage of licensing

2. The permit system relates to the import or export of viable material derived from human embryo clones and is necessary to give effect to the legislative requirements of the *Prohibition of Human Cloning for Reproduction Act 2002* and the related *Research Involving Human Embryos Act 2002*. Viable material means living tissues and cells.

3. The system applies to any viable material derived from human embryo clones originating in Australia or coming from other countries.

4. The *Prohibition of Human Cloning for Reproduction Act 2002* is intended to prohibit the import or export of viable material derived from human embryo clones unless the Minister or an authorised person has granted permission.

5. The relevant legislation is cited above at question 1.

Obtaining a permit under the legislation is a statutory requirement in all circumstances. All materials covered by the definition of "viable material" derived from a "human embryo clone" will require a permit. This is not subject to administrative discretion. The system cannot be abolished without legislative approval.

Procedures

6. Not applicable.

- 7. (a) An application for a licence should be made well in advance of the proposed import or export. As the details of the system have not been finalised it is not possible to provide specific information. However, the time taken to consider an application for a licence will vary depending on the circumstances of the import or export and the completeness of information provided.
- (b) It is unlikely that immediate granting of a permit will be possible given the information required and the time needed to assess it.
- (c) No.
- (d) The NHMRC will have responsibility for administering the permit system and will provide advice to Home Affairs on any permits issued.

8. An application that meets the criteria will be granted a permit. Where an application is refused, reasons are provided and applicants have a right of appeal to the Administrative Appeals Tribunal. In addition, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. (a) Not applicable.

(b) Yes. However, a person or organisation seeking an import permit must satisfy the Authorised Person specified in the regulations that they are capable of complying with any conditions attaching to the permit.

In relation to persons or organisations applying for an export permit it is expected that only the person or organisation that derived the viable material in Australia would be eligible to apply. Such persons or organisations would need to hold a licence issued under the *Research Involving Human Embryos Act 2002* authorising the creation of the human embryo clone and derivation of viable material from it.

Documentation and other requirements for application for licence

10. As noted above the details of the permit system have not been finalised. However, the importer or exporter will be required to demonstrate that the viable material has been obtained using practices consistent with Australian legislation. This will include providing evidence that the viable material has been derived or obtained legally and ethically. Information and application forms will be available from the NHMRC website (<u>http://www.nhmrc.gov.au</u>).

11. An approval under the Legislation, such as a permit, must be obtained prior to import or export and is required to be produced at the time of import or export.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of permits.

Conditions of licensing

14. The period of validity of a permit will be the period set out in the permit. Details are not yet available.

15. No.

16. Given the requirements for obtaining the permit, it is unlikely that the system will allow for transfer of permits between importers or exporters.

17. The regulations allow for conditions to be attached to permits. The details of such conditions have not yet been finalised. Failure to comply with the conditions can lead to revocation of the permit.

Other procedural requirements

18. Customs and quarantine controls may be relevant.

19. Not applicable.

30 WEAPONS AND CROWD CONTROL GOODS

Outline of System

1. The importation of weapons including, daggers, crowd control goods and laser pointers are regulated by the *Customs Act 1901* and the Customs (Prohibited Imports) Regulations 1956.

Purposes and coverage of licensing

2. The goods covered are weapons, crowd control goods and laser pointers as specified at Schedule 13 of the Customs (Prohibited Imports) Regulations 1956 (the Regulations), and firearms, firearm accessories, firearm parts, firearms magazines, ammunition, components of ammunition and imitation firearms as specified in Schedule 6 of the Regulations.

The importation of goods specified in Schedule 13 of the Regulations is prohibited unless the written permission of the Minister for Home Affairs, or an authorised person, is granted. Permission to import Schedule 13 weapons may be granted on the basis that certain conditions or requirements

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are met, such as the goods will only be supplied to law enforcement agencies and the importer holds the appropriate state or territory licence to possess the goods. Applications for permission to import Schedule 13 weapons are processed through the Department of Home Affairs (Home Affairs). Some goods specified in Schedule 13 may be imported with certification from the police in the state or territory of residence.

The importation of goods specified in Schedule 6 is prohibited unless the conditions, restrictions or requirements specified are complied with and the written permission of the relevant authority is granted. Applications for the import of firearms and firearm-related articles are processed either by the Department of Home Affairs (where import permission can be granted by the Minister for Home Affairs or their delegate) or the relevant State or Territory policing agency. Generally speaking, firearms and firearm-related articles falling to lesser import controls can be imported with police certification, while the more highly controlled items require a Commonwealth (Department of Home Affairs) import permit.

3. The regulations apply to importations from all countries.

4. The PI Regulations are not intended to restrict the quantity or volume of imports. Importers must specify the quantity of goods when seeking to apply for single import permission. Ongoing permits can be issued for Schedule 13 goods for projects requiring multiple shipments of goods over a specified period of time. Firearm dealers can also be issued ongoing permits for certain Schedule 6 goods.

Controls on importation have been introduced as a community protection measure. The monetary value is not a criterion for control.

5. The control on importation of the specified goods is a statutory requirement under the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval

Procedures

6. Not applicable.

7. (a) Application must be made in advance of arrival of the goods.

- (b) Applications for permission to import can be processed immediately provided all information is available and the application is considered to be urgent. Permission itself cannot be granted immediately, as the decision-maker must consider whether the importation meets the requirements specified in the Regulations before giving written permission.
- (c) Permits may be issued at any period of the year.
- (d) Where the Commonwealth is the relevant authority for issuing an import permit, the Minister for Home Affairs or their delegate may also require state or territory approval for the possession and sale of the goods. Applications for import permits required under Schedule 13 are processed by Home Affairs or the relevant state or territory Police where appropriate. Applications for import permits required under Schedule 6 are processed by the Department of Home Affairs, or the relevant State or Territory policing where appropriate.

8. Application for permission to import can be refused at the discretion of the relevant Minister, (or their delegate) or police representative. Reasons for refusal are given to applicants. Depending on the circumstance, appeal may be made under the *Administrative Decisions (Judicial Review) Act 1977* or via judicial review applications made to the Federal Court.

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply.

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Documentation and other requirements for application for licence

10. Applications must be made in writing to the relevant authority. The application must include supporting documentation showing the importation complies with the relevant conditions, restrictions or requirements specified. This generally includes confirmation that the goods can be possessed or sold in the relevant State or Territory.

The application form for Schedule 13 goods can be found at: <u>https://www.border.gov.au/Forms/Documents/B710.pdf</u>.

The application form for Schedule 6 goods can be found at: <u>https://firearms.homeaffairs.gov.au/ApplicationForm.aspx</u>

Importers must contact their state or territory police firearms registry when importing items under police certification.

11. A copy of the permission from the relevant authority is required upon importation.

There is no licensing fee for applying to the Department of Home Affairs for an import permit. There is similarly no charge when an import application is subsequently approved or denied.

12. The relevant authority that grants import permission may specify a time period for the validity of the permission.

13. There is no penalty for the non-utilisation of an import permit.

Conditions of licensing

14. Permits and licenses are not transferable between importers.

15. Conditions may be imposed on the import permit, and exact quantities subject to the import are specified.

16.

17.

Other procedural requirements

18. No.

19. Not applicable.

31 WOOLPACKS

Outline of System

1. The importation of woolpacks is prohibited under the provisions of the *Customs Act 1901* and Customs (Prohibited Imports) Regulations 1956 (PI Regulations) unless the permission of the Commonwealth Minister for Agriculture or an authorised person, is granted; or a test certificate issued by a prescribed testing authority certifying that the woolpacks conform to Australian standards, is produced.

Purposes and coverage of licensing

2. Unused woolpacks to be used for greasy wool require a test certificate issued by a prescribed testing authority, certifying that the woolpacks conform to Australian Wool Exchange (AWEX) standard no 3.

Unused woolpacks to be used for purposes other than greasy wool, require an import permission from the Minister for Agriculture or an authorised person. Import conditions (conditions of use) may be applied to these woolpacks.

Second-hand woolpacks require an import permission from the Minister for Agriculture or an authorised person. The importation of second-hand woolpacks for use as containers of greasy wool is not permitted. Conditions of use (see 17.) may be applied to second hand woolpacks.

3. The regulations apply to the importation of woolpacks from all countries.

4. The importation of woolpacks is regulated to ensure adequate pack strength and to minimise fibre contamination of the Australian wool clip. The PI Regulations are not intended to restrict the quantity or volume of imports.

5. The control on importation of the specified goods is a statutory requirement under Regulation 4K of the PI Regulations made under the *Customs Act 1901*. The system cannot be abolished without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) Application should be made in advance of arrival of the goods. In certain circumstances, import permission can be given for goods which have inadvertently arrived at the point of entry.
- (b) Permits may be issued promptly if a genuine emergency exists.
- (c) Permits may be issued at any period of the year.
- (d) A test certificate may be issued by a prescribed testing authority to certify that the woolpacks conform to Australian Wool Exchange (AWEX) standards. Applications for import permission are issued by officers of the Department of Agriculture authorised by the Minister for Agriculture.

8. Application for permission to import can be refused at the discretion of the Minister for Agriculture or an authorised person, if the ordinary criteria are not met. There is no right of appeal against the Minister's (or authorised person's) decision. However, an appeal may be made on the decision-making process itself under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

- 9. (a) Not applicable.
- (b) All persons, firms and institutions are eligible to apply for permission to import.

Documentation and other requirements for application for licence

10. For permission to import applications must be made in writing to the Minister for Agriculture. The application should include the following information:

- importer's name and address;
- details of the goods to be imported;
- quantity and distribution (end use);
- manufacturer;
- port of lading:
- bill of lading number;
- ETA date and place.

11. Proof of authorisation or a Test Certificate is required on importation.

12. There is no licensing fee or administrative charge.

13. There is no deposit or advance payment requirement associated with the issue of licenses.

Conditions of licensing

14. Permits apply to one consignment only.

- 15. There is no penalty for the non-utilisation of a license or a portion of a license.
- 16. Licenses are not transferable between importers.

17. Conditions may be applied regarding the custody, use, disposal or destruction of the imported woolpacks for the purpose of ensuring that they are not used otherwise than for the purpose for which the permission is granted.

Other procedural requirements

18. No.

19. Not applicable.

32 GENETICALLY MODIFIED ORGANISMS

Outline of System

1. The Gene Technology Act 2000 (GT Act), the Gene Technology Regulations 2001 (GT Regulations) and corresponding state and territory laws provide a nationally consistent system to regulate work (dealings) with genetically modified organisms (GMOs) in Australia. This includes the creation or import, transport, disposal, growth and propagation of GMOs.

A number of other Australian government regulators also oversee work with GMOs, depending on the use of the GMO. These regulators include:

- <u>Australian Pesticides and Veterinary Medicines Authority</u> (APVMA) cover agricultural chemicals and veterinary products, including those produced in, or used on, GM crops and live GM veterinary products.
- <u>Department of Agriculture</u> regulate the import and quarantine of all animal, plant and biological products that could pose a risk if they were imported.
- <u>Food Standards Australia New Zealand (FSANZ)</u> cover food issues, including labelling and mandatory pre-market safety assessments for GM foods.
- <u>Therapeutic Goods Administration (</u>TGA) regulate all therapeutics, including those which are GMOs (for example, live GM vaccines).

Legislation governing the other organisations in the list above includes:

- Australian Pesticides & Veterinary Medicines Authority: <u>Agricultural & Veterinary</u> <u>Chemicals Code Act 1994</u> and <u>Agricultural & Veterinary Chemicals (Administration) Act</u> <u>1992</u>
- Department of Agriculture: <u>Biosecurity Act 2015</u> and <u>Imported Food Control Act 1992</u>
- Food Standards Australia New Zealand: <u>Food Standards Australia New Zealand Act 1991</u>
- Therapeutic Goods Administration: <u>Therapeutic Goods Act 1989</u>

Purposes and coverage of licensing

2. The gene technology regulatory scheme covers dealings with all live/viable GMOs as defined in the GT Act and modified by the GT Regulations. The scope of the gene technology legislation covers all aspects of GMOs, including commercial, research and development, and personal use of GMOs.

3. All GMOs, whether created in Australia or imported are covered by the Gene Technology legislation.

4. The gene technology legislation is not intended to restrict the quantity or value of imports but to manage the risks of working with GMOs. In administering the gene technology regulatory system, the Gene Technology Regulator (the GT Regulator), has specific responsibility to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of

gene technology, and by managing those risks through regulating certain dealings with GMOs. The Gene Technology scheme also implements Australia's obligations under Article 8(g) the UN Convention on Biological Diversity.

Voluntary system / industry self-regulation is not appropriate due to the level of public concern over the potential risks posed by GMOs. However, some work with specified categories of GMOs does not require licensing and can be carried out under a notification process with the appropriate institutional oversight (for example using GM cell lines to manufacture GM pharmaceutical products within certified facilities).

5. The nationally consistent legislative scheme for gene technology is comprised of the Commonwealth GT Act and GT Regulations, and corresponding State and Territory legislation.

The scope and nature of gene technology regulation is specified in the GT Act. Schedules contained within the GT Regulations further clarify the scope of the GT Act and specify the type of authorisations required for work with different categories of GMOs.

The legislation was developed in consultation with all Australian jurisdictions and the scheme is supported by <u>the inter-governmental Gene Technology Agreement</u> between the Australian Government and each State and Territory.

It is not possible for the government or executive branch to abolish the systems without legislative approval.

Procedures

- 6. Not applicable.
- 7. (a) The gene technology scheme provides for a number of different kinds of authorisations dependent upon the nature of the GMO and the proposed use: http://www.oqtr.gov.au/internet/oqtr/publishing.nsf/Content/authorisation-for-qmos.

In relation to commercial-scale import of GMOs, in most cases a licence would be required for commercial dealings with a GMO. If the GMO is imported for use within contained facilities (e.g. GM seeds imported for immediate processing into non-viable products) a licence for <u>Dealings Not involving Intentional Release</u> (DNIR) into the environment may be required. DNIR licences carry a 90 working day processing time and approval must be obtained prior to import.

All other commercial dealings where the GMO is likely to be released into the environment would require a licence for <u>Dealings involving Intentional Release</u> (DIR). The GT Regulator must decide whether to issue a DIR licence within 255 working days.

If the GT Regulator is satisfied that a person has come into possession of a GMO inadvertently, the GT Regulator may, with the agreement of the person, treat the person as having made an inadvertent dealings application under section 40A of the GT Act. A person may also apply for a licence under section 40 of the GT Act in respect of an inadvertent dealing. The GT Regulator may issue a temporary licence (no longer than 12 months) to the person for the purposes of disposing of the GMO in a manner which protects the health and safety of people and the environment.

- (b) The Act does not contain provisions for immediate licence approvals.
- (c) Licence applications can be made at any time of the year.
- (d) The Australian GT Regulator, supported by the Office of the Gene Technology Regulator (OGTR), has sole responsibility for issuing licences for work with GMOs.

However, separate approvals would be needed if the end use of the GMO is regulated by another agency, e.g. therapeutic or veterinary products, agricultural products, human food, etc. (see answer to question 1).

Approval for import under the *Biosecurity Act 2015*, from the Department of Agriculture may also be required.

8. Sections 56 and 57 of the GT Act require that the GT Regulator must not issue the licence unless they are satisfied that:

- (i) any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect:
 - (a) the health and safety of people; and
 - (b) the environment; and
- (ii) issuing the licence would not be inconsistent with a policy principle in force under Section 21 of the Act; and
- (iii) the applicant is a suitable person to hold the licence.

The GT Regulator must inform the applicant of the reasons for their decision. A decision not to issue a licence is a reviewable decision under section 179 of the GT Act. Under section 183 of the GT Act, the applicant may apply to the <u>Administrative Appeals Tribunal</u> (AAT) for review of the decision. The AAT is an independent review body with the power to make a fresh decision. There is a time limit of 28 days within which to lodge an application to the AAT.

The applicant can also apply for an order of review in respect of the decision under the *Administrative Decisions (Judicial Review) Act 1977*.

Eligibility of importers to apply for licence

9. Anyone can apply for a licence, however, the GT Regulator is required to consider the suitability of the applicant to hold a licence. Section 58 of the GT Act provides information on applicant suitability.

This includes consideration of capacity to meet licence conditions and relevant convictions (that is, a conviction for an offence against a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment), if:

- (i) the offence was committed within the period of 10 years immediately before the making of the application for the licence; and
- (ii) the offence was punishable on conviction by a fine of \$5,000 or more, or by a term of imprisonment of one year or more.

Documentation and other requirements for application for licence

10. Application forms to work with GMOs can be found on the OGTR website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/apps-for-gmo.

11. A copy of each DIR licence is made available on the OGTR website at <u>http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1</u>. A copy of the licence should accompany all shipments of GMOs unless the licence specifies otherwise.

12. Currently no fees apply to applications for licences under the GT Act.

13. Not applicable.

Conditions of licensing

14. The period of the licence will be determined on a case by case basis during the assessment of the application. Typically commercial licences do not have an expiry date.

15. Licences permit, but do not require, persons to deal with the specified GMOs. All licence conditions must be followed when dealing with GMOs. It is a criminal offence to knowingly breach the conditions of a licence.

16. Section 70 of the GT Act allows for the transfer of a licence. A 90-working day assessment period applies to applications to transfer a licence. When deciding whether to transfer a licence, the GT Regulator must consider the suitability of the receiving applicant to hold the licence.

17. Division 6 of the GT Act contains information on conditions that may apply to a licence. This includes (but is not limited to):

- (i) the scope of the dealings authorised by the licence;
- (ii) the purposes for which the dealings may be undertaken;
- (iii) variations to the scope or purposes of the dealings;
- (iv) documentation and record-keeping requirements;
- (v) the required level of containment in respect of the dealings, including requirements relating to the certification of facilities to specified containment levels;
- (vi) waste disposal requirements;
- (vii) measures to manage risks posed to the health and safety of people, or to the environment;
- (viii) data collection, including studies to be conducted;
- (ix) auditing and reporting;
- (x) actions to be taken in case of the release of a GMO from a contained environment;
- (xi) the geographic area in which the dealings authorised by the licence may occur;
- (xii) requiring compliance with a code of practice issued under section 24, or a technical or procedural guideline issued under section 27;
- (xiii) supervision by, and monitoring by, Institutional Biosafety Committees;
- (xiv) contingency planning in respect of unintended effects of the dealings authorised by the licence;
- (xv) limiting the dissemination or persistence of the GMO or its genetic material in the environment;
- (xvi) requiring the licence holder to inform people of licence requirements;
- (xvii) requiring the licence holder to provide the GT Regulator with relevant information; and

(xviii) allowing the GT Regulator to monitor dealings with GMOs.

Other procedural requirements

18. Not applicable.

19. Not applicable.