Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Export of Human Substances

Applying for a permit under the *Customs (Prohibited Exports) Regulations 1958*

Version 30 November 2023

Contents

About this guidance

This guidance is to assist individuals in determining whether they need a TGA export permit to export goods that are human substances. Specifically, this guidance is for permit applicants and exporters.

‘Human substances’ refers to goods of human origin that may be regulated as biologicals or medicines and which are:

- human body fluids, organs and other tissues; or
- substances derived from human blood

The TGA only issues export permits for goods that are human substances. If you wish to export substances of animal origin or veterinary medicines, see the Australian Government Department of Agriculture and Water Resources website.

The TGA issues permits for the export of human substances under Regulation 8 of the *Customs (Prohibited Exports) Regulations 1958*. Schedule 6 of the *Customs (Prohibited Exports) Regulations 1958* describes goods (categorised into human body fluids, organs, and other tissues or substances derived from human blood) which are prohibited exports without a permit.

Schedule 6 – Goods the exportation of which is prohibited if permission is not granted under regulation 8	
Item	**Description of goods**
1	Human body fluids, organs and other tissue: (a) including a part or constituent of material of that kind, if the internal volume of the immediate container in which the material is packed exceeds 50 ml; and (b) excluding viable material derived from human embryo clones.
2	A substance derived from human blood

Determining if you need a TGA export permit

Whether or not a TGA export permit is required depends on whether the human substance (and volume) falls under item 1 or Item 2 of Schedule 6 of the *Customs (Prohibited Exports) Regulations 1958*), see table below:

Item	Legislative definition (per Schedule 6 of the *Customs (Prohibited Exports) Regulations 1958*	When is a permit required?	Examples of human body fluids, organs and other tissues
1	Human body fluids, organs and other tissue: (a) including a part or constituent of material of that kind, if the internal volume of the immediate container in which the material is packed exceeds 50 ml; and (b) excluding viable material derived from human embryo clones	✘ do **not** need a TGA export permit if the volume of each individual container is **50 mL or less** (even if the total volume of a shipment exceeds 50 mL) ✓ **do need** a TGA export permit when the volume of a container **exceeds 50 mL**	• blood and blood components (red cells, white cells, platelets, plasma, whole blood) • stem cells • bone marrow • urine • body parts • other similar materials • but exclude viable material derived from human embryo clones (refer to 'Other export permit requirements not covered by a TGA export permit' below).
2	A substance derived from human blood	A permit is **always** required for any amount of a substance derived from human blood	• Immunoglobulins • Blood factors e.g. factor VII, VIII and IX

When you do not need a TGA export permit

You do **not** need a TGA export permit to export:

- human breast milk
- human placenta
  - if you are planning to export human breast milk or placenta we suggest that you contact your state or territory department of health regarding their requirements for handling and storage
- human remains or human ashes - for more information see:
  - Australian Government Department of Health website
  - Australian Border Force website

Other export permit requirements not covered by a TGA export permit

- The National Health and Medical Research Council is responsible for issuing permits for the export of viable material (living tissues and cells) derived from human embryo clones, as a prohibited export under Regulation 8A of the *Customs (Prohibited Exports) Regulations 1958*.
- for more information on how to apply for a permit, see:
  - National Health and Medical Research Council website

Responsibilities of applicants and exporters

As an applicant, you are responsible for:

- making an application in writing and providing accurate information on the application form; and
- lodging the application with the Secretary of the Australian Government Department of Health; and
- ensuring that a TGA export permit is obtained prior to export for human substances that require a permit
- ensuring that the permit is provided to the Australian Border Force before or at the time of export

As an exporter, you are responsible for:

- ensuring that the permit has been provided to the Australian Border Force (ABF)
- verifying that the information in the TGA export permit is accurate
- lodging an Export Declaration for the goods being exported, in the Home Affairs Integrated Cargo System (ICS)
  - for information about lodging an Export Declaration, visit the ABF website
- ensuring you are registered in the Home Affairs ICS with an Exporter Australian Business Number (ABN) or Customs Client ID (CCID) number
  - If you do not have an ABN you may need to apply for a CCID either through your licenced customs broker or by completing a B319 ICS Client Registration application form. This form can also be located through the 'Help and Support' page on the ABF Website. Take your completed form and your ID documents to the nearest ABF office.

The permit number for all TGA export permits begins with HBE followed by eleven digits. This number is recorded by an ABF officer at the time of export.

Applying for a TGA export permit

Two types of permits

The TGA issues two types of permits for the purpose of exporting human substances:

- **single-use export permits**
  - for a single instance of exporting, and generally issued for an individual patient
- **annual export permits**
  - for organisations exporting multiple consignments per annum **to a single destination**

Timeframes for permit issue

Single-use export permits

Single-use export permits are generally issued within one working day of receiving an application.

If you require the permit urgently (e.g. on the same day as your request), please email tga.exports@health.gov.au stating the reasons for the urgency.

Annual export permits

Submit your application for an annual export permit **at least one month prior to the expected date of export** (or expiration of an existing annual permit).

Annual export permits are generally issued within one month of receiving an application.

Issuing of permits

Export permits are issued via email. Applicants are responsible for ensuring that the correct contact details and email address are entered into the application form.

Information needed for an application

Single-use permits

To apply for a single-use permit you need to provide the following information:

- name, address, phone number and current email address of applicant
- Exporter Australian Business Number (ABN) or Customs Client ID (CCID) number of the applicant
- good (substance) to be exported
- volume to be exported
- a brief reason for request, for example:
  - travelling overseas, research purposes, clinical use, therapeutic use, laboratory testing
- export destination (including country)
- date of export: the month of export if the exact date is not known
- patient name
- flight and/or courier details

Annual permits

To apply for an annual permit you need to provide the following information:

- name, address, phone number and current email address of applicant
- Exporter Australian Business Number (ABN) or Customs Client ID (CCID) number of the applicant
- good (substance) to be exported
- a brief reason for request
  - e.g. research purposes, clinical use, therapeutic use, laboratory testing

- name and address of overseas destination (including country)
- maximum quantity per consignment
- maximum number of consignments per permit period

You will need to make a separate application for each destination.

Application forms

Please note: as of June 2024 the online form to apply for a permit to export human substances from Australia will no longer be available due to decommissioning of the platform which hosts the online form. All applications for a permit to export human substances from Australia going forward must occur via the downloadable forms (see below) and be emailed via PDF to tga.exports@health.gov.au.

Downloadable forms

There are separate downloadable forms for single-use permits and annual permits, which are available in Microsoft Word versions.

Once completed, email to tga.exports@health.gov.au.

Privacy and personal information

The TGA obtains personal information (such as names and contact details) as part of the permit application process. Personal information is protected by law under the *Privacy Act 1988*, which contains the Australian Privacy Principles.

The TGA is part of the Australian Government Department of Health and is committed to protecting your privacy and personal information. The Department of Health's Privacy Policy contains information about how we comply with the *Privacy Act 1988.*

For further details about how the TGA uses personal information, see personal information in applications relating to export.

Contact details for exporting human substances

For enquiries about the export of human substances, contact the TGA Exports Team.

Over the Christmas shutdown period, emergency contact details are displayed on our home page for emergency situations.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Application Entry Support and Export Section Regulatory Guidance Team	July 2019
V2	Minor changes to bullet points	Application Entry Support and Export Section Regulatory Guidance Team	January 2023
V3	Correction to classification of blood and blood components (red cells, platelets, plasma, whole blood)	Application Entry Support and Export Section Regulatory Guidance Team	February 2023
V3.1	Correction to classification of blood and blood components (red cells, platelets, plasma, whole blood)	Application Entry Support and Export Section Regulatory Guidance Team	April 2023
V3.2	Deletion of online application form information and addition of paragraph indicating applications must occur via PDF and email	Application Entry Support and Export Section Regulatory Guidance Team	November 2023

Therapeutic Goods Administration

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Reference/Publication #