Australian Export Controls and the Life Sciences

A guide to understanding export control laws regarding the physical export, intangible supply, publication or brokering of life sciences related goods, software or technology

Foreword

This Guide has been developed to assist academics, researchers, laboratories and research centres to understand how Australia's export control laws apply to the export, supply, publication or brokering of proliferation-sensitive, life sciences related goods, software and technology.

1 Do export controls apply to you?

The *Defence and Strategic Goods List* (DSGL) is the list that specifies the goods, software and technologies that are subject to export control administered by Defence. A permit is required when exporting, supplying, brokering or publishing 'DSGL-listed items'[1], unless there is an exemption. Controls on life sciences related goods, software and technology listed in the DSGL apply to all sectors in the same way. They are part of a wider national and international regulatory counter-proliferation framework. Compliance with export controls is a serious obligation but it is manageable. This Guide will help you assess if export controls apply to your circumstances.

> **IMPORTANT:** Throughout this guide, where we refer to '*DSGL technology*', without further reference to either goods or software, the term means both "technology" and "software". There will be, however, limited circumstances for researchers in the life sciences sector where the "software" controls will be relevant.

Many activities taking place within the academic community consist of information that is "basic scientific research[2]" or that is "in the public domain". Such information is exempt from export controls. For example, undergraduate teaching will be outside the scope of export controls because teaching generally does not address controlled technology, and the material used for teaching is generally already in the public domain. The same may not be true of postgraduate teaching which may involve applied or experimental research that inherently is not in the public domain. If the postgraduate teaching is based in Australia but will teach students located overseas, the supply of 'DSGL technology' may require a permit if it involves unpublished information. It is important to note that, the supply of 'DSGL technology' from teacher to student within Australia is not subject to export controls.

> **IMPORTANT:** You will not require a permit if:
> - your activity is exempt from permit requirements – When is a permit not required;
> - your 'DSGL technology' is exempted from control – Exemptions to the technology controls;
> - the supply is between the same "person" - Collaborating Internationally;
> - your goods, software or technology are not listed in the DSGL – Summary of life sciences controls in the DSGL; or
> - your 'DSGL technology' is not "required" for the development, production or use of a DSGL-listed item – Understanding the "required" threshold.

Annex 1 contains case studies of scenarios illustrating the circumstances where a permit may, or may not apply.

[1] References to 'DSGL-listed items' in this Guide includes goods, software and technology.
[2] "Basic Scientific Research" is a defined term. Terms in this Guide that are surrounded with double quotation marks are defined terms in the DSGL. A full listing of defined terms used in this Guide is in Annex 2.

2 How do I apply for export advice or an export permit?

Before you apply for a permit with Defence Export Controls, you can conduct your own assessment of whether your goods, software or technology are listed on the DSGL, and whether your activity (the way in which you will be supplying, brokering or publishing) is controlled by the *Defence Trade Controls Act*. This Guide provides information on the types of controls and exemptions that may apply.

STEP 1: The Online DSGL Tool has two key functions; a questionnaire and a search feature. Through a series of Yes/No style questions you can self-assess if your activity is subject to export controls. People who are unfamiliar with export controls may find it easier to first assess if their activity is controlled before searching the DSGL. The search function displays the control item text from the DSGL based on the terms you enter, as well as links to other text that are key to understanding the extent or limits of the controls. The tool can be accessed at https://dsgl.defence.gov.au.

STEP 2: If you are unable to self-assess whether the items are listed on the DSGL, or the exporting, supplying, publishing or brokering activity is controlled, or you are still uncertain, you can submit an "*Application for DSGL/Activity Assessment*" to us. We will send you an assessment of whether the items or activities are controlled, and instructions on what to do next.

STEP 3: If we send you advice that you need to apply for a permit, or you assess that a permit is required, you should submit an "*Application to Export or Supply Controlled Goods and Technology*". We will assess the application and either issue you with a permit, or advise you why a permit is not required.

When you submit an application you should attach documentation that helps us to assess the goods, software and technology, and details of how the export, supply, publication or brokering activity will be undertaken. This assists us to get our assessment right the first time, and so that if we need to contact you we have a good understanding of your application.

Application forms can be downloaded from www.defence.gov.au/deco.

> **IMPORTANT:** You may require a permit if your goods or 'DSGL technology' are listed in the DSGL and no exemptions apply to your circumstances.

3 Overview of export controls

Australia's export control system is part of an international and national effort to stem the proliferation of conventional, chemical, biological and nuclear weapons and the systems that deliver them. Many goods, software and technologies designed for legitimate civil purposes can also contribute to the development of Weapons of Mass Destruction (WMD) or be used for a military end-use. One of the key objectives of export controls is to prevent the misuse of such proliferation-sensitive technology.

Australia is a signatory to many international treaties and conventions, and a member of several export control regimes, all of which serve our national interests and contribute to the global effort aimed at reducing the risk of proliferation. Each export control regime assesses whether goods, software or technologies are able to contribute to a WMD or military end-use and publishes a list of controlled goods, software and technologies.

Australia's control list, the Defence and Strategic Goods List (DSGL), is drawn directly from the control lists agreed to by the export control regimes. The DSGL has two parts; Part 1 is the listing of controlled military items, and Part 2 is the controlled dual-use[3] items. More information on International Export Control Regimes and Treaties, and the DSGL is available at www.defence.gov.au/deco.

> **IMPORTANT:** The listing of goods, software and technologies on the DSGL does not mean that the export, supply, publication or brokering of the item is prohibited; just that a permit may be required.

3.1 What do you mean by export, supply, publication and brokering?

Exporting occurs when 'DSGL-listed items' leave Australia in tangible form, when it is intended that they be landed outside Australia. It includes items that are being sold, for demonstration, for research or teaching purposes, or being returned to a manufacturer or agent for repair. It also includes controlled software and technology stored on a physical medium, such as a USB drive, laptop, hard drive or CD that leaves Australia. Exports include scenarios where the software or technology is stored on a media storage device that is sent via postal service, or is carried in hand-held or checked-in luggage.

Supply occurs when a person in Australia sends or provides access to DSGL-listed software or technology to another person outside of Australia; i.e. the supply of information that is transmitted electronically. Examples of supply include sending DSGL-listed software or technology via email or fax, or providing someone outside of Australia with a password to access DSGL-listed software or technology stored electronically.

Publication is when DSGL-listed software or technology is made available to the public, or to a section of the public, via the internet or otherwise. Publication controls apply to anyone in Australia, or an Australian citizen or resident or Australian organisation located anywhere in the world.

> **EXAMPLE:** The emailing of research that documents the method and steps to alter the pathogenicity of a DSGL-listed pathogen from Australia to a person overseas is a supply and requires a permit. Placing that same set of instructions on a public website for anyone to access is publishing.

Brokering is when a person or organisation acts as an agent or intermediary in arranging the supply of 'DSGL-listed items' between two places located outside of Australia, and they receive a benefit for arranging that supply.

> **IMPORTANT:** Research collaboration will typically not be subject to brokering controls.

Further guidance on each of these activities is available on our website: www.defence.gov.au/deco.

[3] Non-military items which may be used for military purposes are known as 'dual-use' items.

4 When is a permit not required?

The *Defence Trade Controls Act 2012* contains several circumstances where the supply or publication of 'DSGL technology' does not require a permit. In general, discussions and publication of Part 2 'DSGL technology' does not require a permit.

> **IMPORTANT:** If you know or suspect that goods, software and technology will be used in a weapons of mass destruction (WMD) program, or that the supply of 'DSGL technology' will be for a military end use, you should not proceed with the activity without first contacting Defence Export Controls.

4.1 Oral supply

You do not require a permit when orally supplying DSGL-listed software and technology, for example by:

- having a telephone conversation;
- being party to a video conference;
- live streaming; or
- talking to a person at a conference, seminar, or similar event (whether in Australia or overseas).

Most importantly, given the specific and generally high thresholds for any technology to meet the controlled threshold in the DSGL, and given how complex controlled technology is, it is highly unlikely that controlled technology will be conveyed orally.

You will need a permit if you are orally supplying a person access to technology (e.g. providing a password) or the orally-supplied technology will be used in a Weapons of Mass Destruction program or for a military end-use. Please see below for examples:

EXAMPLE:

- **Oral supply exception applies:** Kate has a telephone conference with her research partners in Germany. During that conversation, Kate discusses DSGL technology. The oral supply exception applies and therefore a permit is not required. However, as mentioned above, it is highly unlikely that controlled technology will ever be conveyed orally.
- **Oral supply exception does not apply:** Kate has a telephone conference with her research partners in Germany. During that conversation, Kate orally provides her colleagues with a password to access a cloud server, so that they can share DSGL controlled technology. The oral supply exception does not apply as Kate is providing access to DSGL technology. Therefore, a permit is required.

4.1.1 Presenting at an overseas conference

It is very unlikely you will need a permit to present at a conference or to send (or take) a presentation to a conference. It would be rare for technology contained in a conference paper or presentation to meet the specific thresholds in the DSGL that would make it controlled. DSGL thresholds are very specific and generally high and it would be rare for a conference paper to contain information that met these thresholds. Also, the presentation of slides at a conference would be considered as a publication, so the forwarding of slides to conference organisers would be exempt, as it is a pre-publication supply. Any researcher who believes their conference paper meets the DSGL threshold should contact Defence Export Controls for an assessment.

4.2 Publication of Part 2 DSGL technology

There is no requirement for a permit to publish technology listed in Part 2 of the DSGL. This includes publishing recordings of oral supply that contains Part 2 'DSGL technology'. More detail on publishing 'DSGL technology' is available at our website.

IMPORTANT: Technology that is specially designed for military use (i.e. items listed in Part 1 of the DSGL such as chemical or biological toxic agents, riot control agents and military equipment for the detection of, and protection from, those agents) is treated differently. It is an offence to publish technology that is listed in Part 1 of the DSGL without approval.

4.2.1 Pre-publication supply

The exemption from a permit requirement for publishing 'DSGL technology' that is in Part 2 of the DSGL extends to 'pre-publication' supply activities as well.

EXAMPLE: Sending an early draft of an article for a journal for comment to a co-author or colleague who is in another country will not require a permit.

IMPORTANT: The exemption for pre-publication activities does not extend to Part 1 'DSGL technology'.

4.3 Supplies made to or by prescribed officials

The supply of 'DSGL technology' by, or to, members of the following groups in the course of their official duties does not require a permit:

- Australian Defence Force;
- Australian Public Service employee;
- Australian Federal Police;
- State or Territory police;
- Australian Security Intelligence Organisation employee; or
- Australian Secret Intelligence Service employee.

5 Exemptions (decontrols) to software and technology controls

There are several overarching exemptions which *decontrol* some "software" and "technology" that would otherwise be subject to export control. In Part 1 of the DSGL, the technology exemptions are written as Notes against Item ML22. In Part 2 of the DSGL, there are two General Notes that apply to all software and technology controls, being the General Technology Note and the General Software Note.

These notes **exempt** from export controls:

- Software and technology that is already "in the public domain";
- Technology that is "basic scientific research";
- Software and technology that is the minimum necessary information for patent applications;
- Software that is mass-marketed; or
- Medical equipment that incorporates controlled software.

5.1 Information in the public domain

A permit is not required for information that is in the public domain. Information in the public domain can be:

- published technical papers;
- publications such as books, journals and newspapers that are available from stores or libraries that are accessible to the public;
- subscriptions which are available to any individual who desires to obtain or purchase the published information;
- unlimited distribution at a conference, seminar, trade show or exhibition;
- general information for marketing purposes such as product brochures and company presentations (if it contains intellectual property then it may be controlled technology, but company literature that is in the public domain will not be controlled); or
- information provided by a patent office without restriction in support of a domestic patent application; or
- information on general scientific principles that are commonly taught in schools, colleges and universities.

5.2 Basic Scientific Research

"Basic scientific research" is defined in the DSGL *as experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective*.

There are two approaches which may help to determine if research fits within this exemption – the use of the Australian Bureau of Statistics research definitions, or the use of Technology Readiness Levels (TRLs).

One approach is to assess if the Research meets the criteria of the Australian Bureau of Statistics definitions as being either *pure basic research* or *strategic basic research.* Research that meets either of these definitions will fall within the threshold of "basic scientific research" and will therefore be exempt from permit requirements. In addition, any technology that is derived from that research activity is also not subject to export controls.

The Australian Bureau of Statistics definitions[4] are as follows:

- *Pure basic research* is experimental and theoretical work undertaken to acquire new knowledge without looking for long term benefits other than the advancement of knowledge, and
- *Strategic basic research* is experimental and theoretical work undertaken to acquire new knowledge directed into specified broad areas in the expectation of useful discoveries. It provides the broad base of knowledge necessary for the solution of recognised practical problems.

[4] Australian Bureau of Statistics (2008) - Australian Standard Research Classification (ASRC).

An alternative approach is the assessment of the maturity of the technology being researched using Technology Readiness Levels (TRLs). Technology Readiness Levels is a methodology that is used to determine the maturity of technology as it moves through its lifecycle from research and development through to production and deployment. Technology Readiness Levels are based on a scale from 1 to 9 with 9 being the most mature technology.

In the context of the life sciences, research and technology that is at levels 1 or 2 will not require a permit. As the technology reaches levels 3 or 4 in its maturity, a permit may be required but an assessment should be conducted to confirm that view. Technology at levels 5 and above will *usually* have met the threshold of being technology "required" for the "development" or "production" or "use" of a 'DSGL-listed item'. Unless an exemption applies, technology at these levels will require an export permit.

A table describing the Technology Readiness Levels in more detail is at Annex 3.

5.3 Minimum necessary information for patent applications

This exemption applies to the export or supply of 'DSGL technology' for the purpose of seeking a patent in Australia or overseas. Seeking a patent includes lodging a patent application and the supply of 'DSGL technology' to a person or organisation (e.g. a Patent Office, patent attorney, research collaborator or a patent review panel) that is directly associated with the lodging (or potential lodging) of a patent application, or as a result of the patent examination process.

Supply for a purpose that is not directly related to seeking a patent will require a permit (unless other exemptions apply); for example, the supply of 'DSGL technology' to a research collaborator located overseas before a decision is made to seek a patent.

Once a provisional patent application is filed, any supplies of 'DSGL technology' to further develop an invention prior to preparing/submitting a complete patent application will require a permit. The supply of 'DSGL technology' for the purpose of locating investors and determining overseas markets (including forwarding a recently-filed provisional application) will require a permit.

The process of publishing a patent[5] (or an unsuccessful application) into the public domain is covered by this exemption. Until such time as that information exists in the public domain, it is still controlled and would require a permit to be supplied if it is not for the purpose of seeking a patent and no other exemptions apply.

5.4 Medical equipment

A permit is not required for Part 2 (Dual-use) 'DSGL-listed items' when such items are incorporated into equipment that has been specially designed for medical end-use. Specially designed for medical end-use means that the equipment is designed for medical treatment or the practise of medicine, but it does not include equipment for medical research.

[5] Note: This exemption does not apply to, and can not be used to circumvent, patents or patent applications that are covered by a Prohibition of Publication under Sections 173-174 of the *Patents Act* (1990).

6 Collaborating internationally

It is important to note that much of the collaboration activities taking place within the life sciences academic and research community consist of information that is "basic scientific research" or that is already "in the public domain". Such information is exempt from export controls. Increasingly, research is conducted through the combined efforts of researchers located around the world, and Australian researchers will be located in different countries while conducting their research.

Different permit obligations will apply depending upon the actual circumstances of the relationship and the means by which any supply activity between a person in Australia and a person who is overseas occurs.

A permit is not required if the sender and recipient are the same "person". The definition of "person" includes supplies between employees of the same body corporate (including an institution), wherever located. Australian companies that are part of multinational corporations should note though, for the purposes of the legislation a body corporate extends only to the Australian registered entity.

> **EXAMPLE:** A permit is not required when a researcher, working on a DSGL-listed pathogen, uploads controlled technology to a shared environment and that same researcher later accesses that technology while overseas.

> **EXAMPLE:** A permit is not required when a researcher, working on a DSGL-listed pathogen, uploads controlled technology to a shared environment which is then accessed by another researcher employed by the same institution while overseas.

Researchers that are part of multinational research collaborations efforts will often use various collaborative methods of sharing 'DSGL technology' rather than point-to-point transfers such as email or file transfer. A common situation is where the researchers store the research findings in a shared environment (e.g. server, server hub, repository, document sharing program or online data sharing environment).

> **IMPORTANT:** Export controls are not determined by where the 'DSGL technology' is stored, or where that storage is located. Instead, it depends on whether a person in Australia supplies, including giving access to, 'DSGL technology' to a person outside Australia – regardless of the method.

> **EXAMPLE:** Dropbox®, a U.S. based company, is not being 'supplied' with technology when you upload it to a personal box, therefore this activity does not require a permit.

A "person" located in Australia makes a supply when doing one of the following things:

- Creates new 'DSGL technology' and uploads it to a shared environment so that it becomes accessible by an individual or a foreign corporate entity outside Australia;
- Downloads 'DSGL technology' from this shared environment, conducts further research and then uploads the outcome of that additional research so that it becomes accessible by an individual or a foreign corporate entity outside Australia;
- Contributes to furthering 'DSGL technology' while it remains in the shared environment using remote access technology (i.e. without actually downloading the technology), and that 'DSGL technology' continues to be accessible by an individual or a foreign corporate entity outside Australia; or
- Provides the username/password or other information required to gain access to this shared environment to an individual or a foreign corporate entity located outside Australia, even if they provide this information orally.

7 Summary of life sciences controls in the DSGL

The DSGL contains a number of specific controls related to biological and chemical goods and technology. Below are links to the relevant biological and chemical controls which can be viewed via the Online DSGL Tool at https://dsgl.defence.gov.au.

7.1 Controls for biological materials

All biological weapon agents that are listed in Part 1 (ML7.a) are controlled. These are biological materials that are adapted or configured to produce casualties in humans or animals, degrade equipment or damage crops or the environment. In addition, Part 1 of the DSGL controls particular "software" (ML21) and "technology" (ML22) for the "development", "production" and "use" of biological weapon agents listed in ML7.a.

Dual-use controlled biological materials listed in Part 2 of the DSGL comprise:

- human pathogens – including viruses, bacteria, toxins and fungi;
- animal pathogens – including viruses and mycoplasmas; and
- plant pathogens – including viruses, bacteria and fungi.

The controls apply to natural (wild type), enhanced and modified (including genetically modified) biological materials; those made via synthetic biology; and apply to both "isolated live cultures" and deliberately inoculated or contaminated living material. The specific pathogens are listed in 1C351 (human), 1C352 (animal) and 1C354 (plant). In addition, Part 2 of the DSGL controls "technology" (1E001) for the "development" and "production" of listed dual-use biological materials. Written nucleic acid sequences of controlled biological materials are not controlled.

IMPORTANT: There are no controls on technology that is for the use of a pathogen.

There are also controls (1C353) for genetic elements[6] and genetically modified organisms that contain nucleic acid sequences from DSGL-listed pathogens that are either associated with pathogenicity (either increasing or decreasing pathogenicity) or are responsible for the coding of DSGL-listed toxins.

To future-proof for advances in emerging technologies such as synthetic biology, controlled pathogens remain controlled even if they have been inactivated (unless it can be confirmed by the exporter that sufficient disruption has taken place that no infectious nucleic acid fragments remain).

IMPORTANT: "Vaccines" are exempt from control if they are in a pharmaceutical formulation that is licensed by, or has marketing or clinical trial authorisation by a regulatory authority.

7.2 Controls for chemicals

Part 1 of the DSGL controls chemical weapon agents (ML7.b) and precursors (ML7.c), and riot control agents (ML7.d). Software (ML21) and technology (ML22) for the "development", "production" and "use" of Part 1-listed chemical weapon agents and precursors and riot control agents is also controlled.

Part 2 of the DSGL controls certain chemicals (1C350) that can be used as chemical weapon precursors, and certain toxic chemicals (1C450). Technology for the "development" and "production" of Part 2-listed, dual-use chemicals (1E001) is also controlled.

[6] *Genetic elements* include, *inter alia*, inactivated organisms (unless it can be confirmed by the exporter that sufficient disruption has taken place that no infectious nucleic acid fragments remain), chromosomes, genomes, plasmids, transposons, and vectors whether genetically modified or unmodified, or chemically synthesized in whole or in part and irrespective of the presence or absence of regulatory regions.

IMPORTANT: This Guide does not cover chemicals that are known primarily as energetic materials including explosives, propellants and oxidisers. These chemicals are listed in ML8, ML908 and 1C111.

7.3 Controls on biological and chemical equipment

Part 1 of the DSGL controls all military equipment designed for the handling, detection, protection, dissemination and decontamination of biological weapon agents or chemical warfare agents (ML7.e - ML7.i). Software (ML21) and technology (ML22) for the "development", "production" and "use" of military equipment designed for the handling, detection, protection, dissemination and decontamination of biological weapon agents or chemical warfare agents is also controlled.

Part 2 of the DSGL controls dual-use biological equipment (1A004 and 2B352) and dual-use chemical equipment (1A004, 2B350 and 2B351). Technology (1E002.g, 2E001, 2E002 and 2E301) for the "development", "production" and "use" of biological and chemical equipment is also controlled. Software (1D003, 2D001 and 2D351) for the "development" and "production" of biological and chemical equipment and software for the "use" of certain biological and chemical detection systems is also controlled.

IMPORTANT: The DSGL contains *Notes* which provide guidance on how to interpret control text. *Notes* may apply to a Part, Category Item or sub-item. The *General Technology Note* and the *General Software Note* apply to all technology and software controls in Part 2 of the DSGL. See Annex 4 for further information on General Notes.

8 Understanding the "required" threshold

When combined, the control listing for a DSGL technology item and the General Technology Note limit the technology that is subject to export control to only *that specific information that is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions of a controlled item* that is necessary for the "development", "production" or "use" of the controlled goods or software. Each control item text will identify whether it is the technology for the "development", "production" or "use" of the controlled item that is subject to control. The fact that the technology is intended for civilian use does not remove the requirement to seek a permit, though it would be relevant to whether a permit would be granted.

When assessing if technology is subject to control, it is important to determine if the technology is "required" for the "development", "production" or "use" of a DSGL listed good. If the technology is not specific or detailed enough to be directly used to develop or produce a listed chemical, pathogen, toxin, genetic element or genetically modified organism, that technology is not controlled because it has not met the "required" threshold.

A similar distinction can be made between experimental research activities and commercial-scale production. The experimental or theoretical pursuit of new knowledge or observable facts or phenomena is generally insufficient to meet the "required" threshold (as opposed to technology for proprietary research and industrial development, design, and production technology). The latter will generally require a permit, unless an exemption applies.

> **EXAMPLE:** Control Item 1C351.d.1 lists botulinum toxin. All forms of botulinum toxins are controlled except pharmaceutical formulations that are pre-packaged and authorised for distribution as medical products. A botulinum vaccine would also be exempt from control[7].
>
> The related technology control, 1E001, only applies to the technology that can be considered "required" for the "development" or "production" of botulinum. Instructions on how to extract and purify botulinum toxins will only meet the "required" threshold if they are unique to botulinum toxins. If the instructions are generic with other non-controlled toxins then the threshold is not met and will not be controlled.

Controlled "technology" may take the form of blueprints, plans, diagrams, models, formulae, tables, designs and specifications, or manuals and instructions, either written or recorded on other media or devices such as disks, tapes or read-only memories. It can also include instruction, skills, training, working knowledge or consulting services that involve the transfer of "technology".

[7] "Vaccines" are exempt from control if they are in a pharmaceutical formulation that is licensed by, or has marketing or clinical trial authorisation by a regulatory authority.

9 Record-keeping requirements and reporting

The DTC Act requires a permit holder to *keep* records of the activities that are conducted under the permit for 5 years. There are various approaches that a permit holder can take to meet their obligation to keep a record of a supply, and these include:

- keeping copies of the supply activity, e.g. saving the email which contains the permit number along with the details of the technology and recipient;
- maintaining a register/log of supply activities, e.g. a spreadsheet with columns for the permit number, software or technology description, end-user/recipient, date supply commenced, and date supply ceased; or
- making a note when the first supply activity occurs and a similar note when the supply activity concludes, or the permit expires.

Similar obligations to keep records of exported goods apply to permits issued under the *Customs Act*. In these circumstances, the obligation can be met by options including keeping a record of the commercial documentation that is generated to send the goods by sea, air or post.

Some permits have a condition that requires the permit holder to *submit a report* to us on the activities that occurred during a particular period. This condition will be clearly stated on the permit when it is issued. We will send you reminders when a report is due, and reminders if you do not submit your report in the required timeframe.

10 Where can I get more information?

More information on the export controls administered by Defence Export Controls, as well as the application forms required to apply for a permit, can be found at www.defence.gov.au/deco

Email: deco@defence.gov.au

Phone: 1800 66 10 66

Annex 1: Case Studies

My company supplies small quantities of triethanolamine to overseas universities for research purposes. As the quantities are small (a few ml), do I still require export approval?

Triethanolamine is listed in Control Item 1C350.46. As there is no minimum threshold, a permit would be required. The only exception would be if the triethanolamine was part of a mixture. There is a note at the end of the Control Item text that de-controls (exempts) the mixture if the triethanolamine comprises 30% or less of the mixture, in which case the mixture would not require an export permit.

There are several other de-control notes that apply to the chemicals listed in Control Items 1C350 and 1C450. If a de-control note applies, then a permit does not need to be obtained.

My research requires using a live strain of Lassa fever virus and I would like to share my research findings with collaborators overseas. I will not export the actual strain as my collaborators have their own. Do I require a permit to provide the research to my collaborators?

Merely using a controlled pathogen does not inherently make the research controlled and there are no "use" technology controls for pathogens. Controls only apply to "development" and "production" technology, and do not apply to technology in the public domain. Therefore the technology would only be controlled if you were disclosing to collaborators a novel method to develop or produce the pathogen (this includes technology for enhancing or modifying the pathogen). In addition, the technology would only be controlled if it was specific to Lassa fever virus; "development" and "production" technology that is generic with non-controlled pathogens is not controlled.

I am emailing results of Shiga-like Toxin producing E.coli (STEC) to a Quality Assurance Program overseas (including information on culturing strains. Do I need a permit?

From this scenario information, it is difficult to be definitive on whether a permit will be required. More detail is needed regarding the 'emailing of results' and what that information contains. This will determine whether the information meets the "required" technology threshold. The information regarding the 'culturing of strains' of Shiga-like Toxin producing E.coli (STEC) may require a permit if the information contains instructional detail on how to develop or produce a controlled pathogen and that information is not already in the public domain.

I need to export genomic segments of Choclo virus. I note that genetic elements are only controlled in 1C353 if they contain a nucleic acid sequence associated with pathogenicity. How do I make this determination?

In this case 'associated with pathogenicity' is elaborated on in Technical Note 2 to 1C353. This includes any specific sequence that either in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health, or is known to enhance the ability of a listed pathogen or any other pathogen into which it may be inserted or otherwise integrated, to cause serious harm to humans, animals or plant health.

I work for the Australian subsidiary of a European pharmaceutical company. We are developing a vaccine for Nipah virus. Do I need a permit to cover all my interactions with colleagues overseas?

Nipah virus is controlled in Control Item 1C351.a.25, and so is technology for its "development" and "production". Although there is an exemption for "vaccines" (1C351 Note), this only applies to products in pharmaceutical formulations that are licensed by, or have marketing or clinical trial authorisation from regulators. Sending any 'DSGL technology' to a colleague who is an employee of the European company would require a permit. If you were to send the same technology to a colleague who is an employee of the same Australian company, but who is temporarily working at the European company, a permit is not required as the supply is to the same "person" (i.e. between employees of the same Australian company).

A permit is required for the export of any living samples of the virus that are not pharmaceutical formulations, and any novel technology that is for the "development" or "production" of Nipah virus (which includes enhancing and modifying). Technology that is generic with non-controlled pathogens is not controlled.

My research involves performing nucleic acid sequencing of controlled pathogens. Do I need a permit to provide the sequences to overseas collaborators?
No. Written nucleic acid sequences are not controlled, even if they are not in the public domain.

My research doesn't involve a controlled pathogen, but involves using a fermenter that is controlled. DSGL Item 2E301 controls technology for the "use" of controlled fermenters - does this mean my research is controlled and requires a permit to send to overseas collaborators?
No. The "use" technology controls are applicable only to the controlled equipment, not research that is done using controlled equipment. Using controlled equipment in research does not influence the control status of the research. In this case "use" technology for the fermenter would include a maintenance manual or user manual. However, any technology that is in the public domain is not controlled - the majority of "use" technology is expected to be non-proprietary and available in the public domain, and hence not controlled.

I'm doing research related to a current pandemic that involves a controlled pathogen. My research is specifically on the synthesis of proteins for use in antibody-based assays. This technology could be used for the development of the controlled pathogen. As technology for the "development" and "production" of the pathogen is controlled, does this mean my research requires a permit in order to share with international collaborators?
Not all technology that could feasibly contribute to the "development" or "production" of a controlled pathogen is controlled. The threshold test used is, *is the technology specific or detailed enough to be solely relied on to develop or produce a listed chemical, pathogen, toxin, genetic element or genetically modified organism?* If the answer is yes, that technology has met the "required" threshold and is controlled and will require an export permit. In this case, the technology is too generic and far removed - a lot more work and knowledge would be required.

I export inactivated controlled pathogens. Would I still require a permit for their export?
Yes. Controlled pathogens remain controlled even if they have been inactivated (unless it can be confirmed by the exporter that sufficient disruption has taken place that no infectious nucleic acid fragments remain). Genetic elements[8] associated with the pathogenicity or toxicity of 'DSGL-listed items' are also controlled. This includes intact, naturally derived or synthetically produced nucleic acid which codes for a toxin or a pathogenic determinant that is readily recoverable such as a microbial lysate or purified nucleic acid.

I am researching conotoxin for use in pharmaceutical applications. As this is a controlled toxin, does this mean all my research is controlled and requires a permit?
A pharmaceutical formulation of conotoxin would be exempt if it is pre-packaged and authorised for distribution as a medical product (Note 2 to 1C351). In addition, a conotoxin vaccine would also be exempt from control, provided it was in a pharmaceutical formulation and had regulatory authorisation as per the "vaccine" definition.

Examples of aspects of technology that would be controlled are:

- technology describing methods for isolating the active peptides, if not in the public domain (technology exemptions would include public domain information specific to conotoxins or technology that is generic with non-listed toxins);
- technology on how to modify a conotoxin (including decreasing or increasing its pathogenicity), if not in the public domain;
- technology on how to produce a conotoxin via synthetic biology, if not in the public domain (however written nucleic acid sequences are not controlled); and
- technology on how to produce large quantities of a conotoxin (e.g. for vaccine mass-production), whether though synthetic biology or traditional growth methods.

[8] *Genetic elements* include, *inter alia*, inactivated organisms (unless it can be confirmed by the exporter that sufficient disruption has taken place that no infectious nucleic acid fragments remain), chromosomes, genomes, plasmids, transposons, and vectors whether genetically modified or unmodified, or chemically synthesized in whole or in part and irrespective of the presence or absence of regulatory regions.

I am taking a laptop overseas with manuscripts involving DSGL-listed organisms. I am meeting with collaborators and will be sharing information. Do I need a permit?

Firstly, it is unlikely that the manuscripts on the laptop contain controlled technology. The controlled threshold for 'DSGL technology' is high and a number of exemptions apply (such as 'pre-publication activities'; 'in the public domain'; being considered 'Basic Scientific Research' and meeting the 'required' threshold – all these exemptions are discussed in this Guide).

If a person stores controlled 'DSGL technology' on a laptop, Defence advises that a permit should be obtained before the laptop is taken out of Australia. The permit would give permission for a person to take the controlled 'DSGL technology' stored on the laptop outside Australia, provided it is for their personal use and not to be transferred.

It is important to note that the laptop itself is not controlled; it is only because controlled 'DSGL technology' is stored on the device.

Defence is currently working with the Department of Immigration and Border Protection and drafters in the Office of Parliamentary Counsel to amend the export control regulations so that this permit requirement is removed. Until such time, a permit would be required if the laptop stores controlled 'DSGL technology'.

I am presenting at an overseas conference on a DSGL-listed organism. Do I need a permit?

It is very unlikely you will need a permit to present at a conference or to send (or take) a presentation to a conference. It would be rare for technology contained in a conference paper or presentation to meet the specific thresholds in the DSGL that would make it controlled. DSGL thresholds are very specific and generally high and it would be rare for a conference paper to contain information that met these thresholds. Also, showing the slides at the conference would be a publication, so the forwarding of the slides to the conference organisers would be exempt as it is considered to be a pre-publication supply. Any researcher who believes their conference paper meets the DSGL threshold should contact Defence Export Controls for an assessment.

Annex 2: Definitions used in this Guide

"**Basic scientific research**" means experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.

"**Development**" is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts.

"**In the public domain**", as it applies herein, means "technology" or "software" which has been made available without restrictions upon its further dissemination (copyright restrictions do not remove "technology" or "software" from being "in the public domain").

"**Isolated live cultures**" includes live cultures in dormant form and in dried preparations.

"**Microorganisms**" means bacteria, viruses, mycoplasma, rickettsia, chlamydiae or fungi, whether natural, enhanced or modified, either in the form of isolated live cultures or as material including living material which has been deliberately inoculated or contaminated with such cultures.

"**Object code**" means an equipment executable form of a convenient expression of one or more processes ("source code" (source language)) which has been converted by a programming system.

"**Person**" (relevant to Australia) means:

(a) the Commonwealth, a State or a Territory or an authority of the Commonwealth, a State or a Territory; or
(b) an individual who is an Australian citizen; or
(c) an individual who is, within the meaning of the Migration Act 1958, the holder of a permanent visa; or
(d) a body corporate incorporated by or under a law of the Commonwealth or of a State or Territory.

"**Production**" means all production phases, such as: construction, production engineering, manufacture, integration, assembly (mounting), inspection, testing, and quality assurance.

"**Required**", as applied to "technology", refers to only that portion of "technology" which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions. Such "required" "technology" may be shared by different goods.

"**Software**" means a collection of one or more "programs" or 'microprograms' fixed in any tangible medium of expression. [Note: 'Microprogram' means a sequence of elementary instructions, maintained in a special storage, the execution of which is initiated by the introduction of its reference instruction into an instruction register.]

"**Technology**" means specific information necessary for the "development", "production" or "use" of a product. This information takes the form of 'technical data' or 'technical assistance'. Controlled "technology" for the Dual-Use List is defined in the General Technology Note and in the Dual-Use List. Controlled "technology" for the Munitions List is specified in ML22.

Note 1: 'Technical assistance' may take forms such as instruction, skills, training, working knowledge and consulting services and may involve the transfer of 'technical data'.

Note 2: 'Technical data' may take forms such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read only memories.

"**Toxins**" means toxins in the form of deliberately isolated preparations or mixtures, no matter how produced, other than toxins present as contaminants of other materials such as pathological specimens, crops, foodstuffs or seed stocks of "microorganisms".

"**Use**" means operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.

"**Vaccine**" is a medicinal product in a pharmaceutical formulation licensed by, or having marketing or clinical trial authorisation from, the regulatory authorities of either the country of manufacture or of use, which is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Annex 3: Technology Readiness Levels

Technology Readiness Levels are a way of determining the maturity of technology as it moves through its lifecycle from research and development through to production and deployment. Technology Readiness Levels are based on a scale from 1 to 9 with 9 being the most mature technology.

	Technology Readiness Level	Description	Permit Required
Research and Development	1	**Review of Scientific Knowledge Base** • Research at this level would be "Basic Scientific Research". • The export or supply of technology would not require a permit.	No
	2	**Development of Hypotheses and Experimental Designs** • Research at this level would be "Basic Scientific Research". • The export or supply of technology would not require a permit.	No
	3	**Target/Candidate Identification and Characterisation of Preliminary Candidate(s)** • Research at this level may no longer be "Basic Scientific Research". • The export or supply of technology may require a permit.	Maybe
Testing and Demonstration	4	**Candidate Optimisation and Non-Good Laboratory Practice In Vivo Demonstration of Activity and Efficacy** • Research at this level could be "Basic Scientific Research", but may be closer to applied research. • A permit may be needed for technology that is deemed "required" and is not "basic scientific research".	Maybe
	5	**Advanced Characterisation of Candidate and Initiation of Good Manufacturing Practice (GMP) Process Development** • Research at this level would usually be applied or experimental research. • A permit may be required for the supply of technology and the export of any goods and technology.	Yes (if no exemptions apply)
	6	**GMP Pilot Lot Production, Therapeutics Goods Administration Registration, and Phase 1 Clinical Trial(s)** • Research at this level would usually be applied or experimental research. • A permit may be required for the supply of technology and the export of any goods and technology.	Yes (if no exemptions apply)
Production and Deployment	7	**Scale-up, Initiation of Good Manufacturing Practice Process Validation, and Phase 2 Clinical Trial(s)** • Research at this level would usually be applied or experimental research. • A permit may be required for the supply of technology and the export of any goods and technology.	Yes (if no exemptions apply)
	8	**Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and TGA registration of good** • Research at this level would usually be applied or experimental research. • A permit may be required for the supply of technology and the export of any goods and technology.	Yes (if no exemptions apply)
	9	**Post-Licensure and Post-Approval Activities** • Research at this level would usually be applied or experimental research. • A permit may be required for the supply of technology and the export of any goods and technology.	Yes (if no exemptions apply)

Annex 4: Notes in the DSGL that apply to controlled items

The DSGL contains Notes which provide guidance on how to interpret a control text. Notes may apply to a Part, Category Item or sub-item. The *General Technology Note* and the *General Software Note* apply to all technology and software controls through Part 2.

General Technology Note

This note applies to all technology controls in Categories 1 to 9.

1. The export of "technology" which is "required" for the "development", "production" or "use" of goods controlled in Categories 1 to 9, is controlled according to the provisions of Categories 1 to 9.

2. "Technology" "required" for the "development", "production" or "use" of goods under control remains under control even when applicable to non- controlled goods.

3. Controls do not apply to that "technology" which is the minimum necessary for the installation, operation, maintenance (checking) and repair of those goods which are not controlled or whose export has been authorised.

   Note: This does not release such "technology" specified in 1E002.e., 1E002.f., 8E002.a. and 8E002.b.

4. Controls on "technology" transfer do not apply to information "in the public domain", to "basic scientific research" or to the minimum necessary information for patent applications.

General Software Note

This note applies to all software controls within Categories 0 to 9.

Categories 0 to 9 of this list do not control "software" which is any of the following:

1. Generally available to the public by being:
   a. Sold from stock at retail selling points, without restriction, by means of:
      1. Over-the-counter transactions;
      2. Mail order transactions;
      3. Electronic transactions; or
      4. Telephone order transactions; and
   b. Designed for installation by the user without further substantial support by the supplier;

   Note: Entry 1. of the General Software Note does not release "software" specified in Category 5 — Part 2 ("Information Security").

2. "In the public domain"; or

3. The minimum necessary "object code" for the installation, operation, maintenance (checking) or repair of those items whose export has been authorised.

   Note: Entry 3 of the General Software Note does not release "software" controlled by Category 5 — Part 2 ("Information Security").