**Production questionnaire: Cell lines (including genetically modified cell lines)**

**Form authorised for the request of information under the *Biosecurity* *Act 2015***

* 1. **Section A: General information**

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| --- | --- |
| **Purpose of this form** | To support an [import permit application](https://www.agriculture.gov.au/import/online-services/bicon) by an Australian entity or individual to import **cell lines (including genetically modified cell lines)** into Australia. |
| **Who should complete this form** | Review the scenarios below to determine who must complete this form:

|  |  |
| --- | --- |
| * Goods **have not** undergone any manufacturing/processing (e.g., animal tissue samples) and sourced from specific supplier/s
 | This form must be completed by the supplier of the goods. This must be an individual or authorised representative of a company who sampled/collected the goods intended for import into Australian territory and can attest to the health of the source animals if required. |
| * Goods **have not** undergone any manufacturing/processing (e.g., animal tissue samples) and/or **not sourced from specific supplier/s** i.e., sourcing of goods needs to be flexible
 | This form can be completed by the importer of the goods. Note that resulting import conditions may be more restrictive and/or more detailed consignment-specific evidence may be required to evidence the goods meet import conditions.  |
| * Goods **have** undergone manufacturing/processing into a fully finished product i.e., with a brand/product name or code (e.g., antisera)
 | An authorised representative of the **physical manufacturer\*** of the goods must complete this form. \*The department defines a physical manufacturer’ as the facility where the products are manufactured. This includes buildings and areas where the products are stored or processes and any other buildings or areas within the boundary of the site.OR |
| * Goods **have** undergone manufacturing/processing into a fully finished product i.e., with a brand/product name or code (e.g., antisera) continued…
 | If the form cannot be completed by an employee of the physical manufacturing site, the form can be completed by an authorised representative of the **legal manufacturer.** The signee must provide sufficient documentation in relation to:* the manufacturing of the goods,
* the locations of the physical manufacturing sites and head office
* evidence that the entity signing/supplying the manufacturers declaration has adequate oversight of the manufacturing process and would have the capacity to notify the department should any change, in the sourcing or manufacturing process of the products, occur.

This evidence may include standard operating procedures (SOPs) and/or evidence of oversight/control of manufacturing processed and sourcing of ingredients. This evidence must be supplied in addition to, and accompanying, this production questionnaire. |

 |
| **To complete this form** | Answer all questions truthfully and accurately. Failure to complete questions or provide supporting documentation will result in delays in the processing of the import permit application.**Electronically**Download the document to your computer and save any changes.**Manually**Use black or blue penPrint in BLOCK LETTERSMark boxes with a tick þ or a cross ýAttach additional sheets if space is insufficient**Any additional documents must be:** * on the manufacturer’s letterhead (including company address and country).
* signed by a senior company employee from the site of manufacture (or legal manufacturer with evidence supplied), whose name, title and contact details also appear.
* dated within the last 6 months, free from erasures and uncertified alterations (all alterations must be initialled by the senior company employee responsible for signing the declaration).

All documentation supplied in support of an import permit application is required to meet the department’s [minimum documentary and import declaration requirements policy](https://www.agriculture.gov.au/import/arrival/clearance-inspection/documentary-requirements/minimum-document-requirements-policy). |
| **To submit this form** | **Option 1 (preferred)**Submit your completed, signed questionnaire and all additional documents and attachments to the Australian importer for inclusion in their import permit application.**Option 2 Questionnaires containing commercial-in-confidence information**All commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law.Post or email (preferred) the completed questionnaire and all additional documents and attachments (referencing the import permit application number and marked ‘commercial-in-confidence’ where relevant) to:Biosecurity Import Services TeamDepartment of Agriculture, Fisheries and Forestry GPO Box 858Canberra ACT 2601Email Imports@aff.gov.au |
| **More information** | Phone 1800 900 090 (within Australia)+61 3 8318 6700 (outside Australia)Email Imports@aff.gov.au |

## Section B: Contact details

1. **Details of authorised representative completing this form**

|  |  |
| --- | --- |
| **Legal entity name** |  |
| **Authorised person to sign this form *(must be an employee of the facility)*** | **Full name:**  | **Position in company/Job title:** |
| **Select applicable option** | [ ]  Physical manufacturer [ ]  Legal manufacturer[ ]  Supplier [ ]  Importer [ ]  Other (provide details):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

1. **Facility where products are manufactured (if the same as question 1, write ‘As above’). Include multiple facilities if required.**

|  |  |
| --- | --- |
| **Legal entity name** |  |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

1. **Exporter’s details (if exporter and manufacturer details are the same, write ‘As above’)**

|  |  |
| --- | --- |
| **Legal entity name** |  |
| **Address** |  |
| **Phone (include area code):**  |  | **Fax:** |  |
| **Email:** |  |

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## Section C: Product to be exported to Australia

**If you are exporting multiple products, provide a separate version of this section for each product.**

1. **List the cell line/s name and its species of origin:**

| **Cell line name** | **Species of origin** | **Country of origin** | **Is the cell line and/or supernatant fluid greater than 2 years old?** |
| --- | --- | --- | --- |
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1. **Have the cell line/s been inoculated with microorganisms or infectious agents (other than the virus used to immortalise the cell line)?**

[ ]  Yes – please complete the table below.

[ ]  No – go to question 6.

|  |  |
| --- | --- |
| **Genus and species of microorganisms or infectious agents cell line is inoculated with** | **Will the cell line be used to:*** **culture and isolate the microorganism or infectious agent?**
* **Synthesise replication competent homologues of the microorganism or infectious agent?**
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1. **Have the cell line/s shown signs of cytopathic effects with adventitious infectious agents or microbial contamination?**

[ ]  Yes – please complete the table below.

[ ]  No – go to question 7.

|  |  |
| --- | --- |
| **Genus and species of microorganisms or infectious agents** | **Will the cell line be used to:*** **culture and isolate the microorganism or infectious agent?**
* **Synthesise replication competent homologues of the microorganism or infectious agent?**
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1. **Have the cell line/s been genetically modified (other than immortalisation)?**

[ ]  Yes – go to question 8.

[ ]  No – go to question 13.

### **How is the genetic material introduced into the cell line/s?**

[ ]  Transfection using chemical, mechanical or electrical means

[ ]  Transduction using a viral vector – please provide information on the viral vector/s used below, including genus/species and whether the vector is replication competent

1. **How is the genetic material incorporated into the genome of the cell line/s?**

[ ]  Nucleic acid insertion into the genome of the cell line mediated by nucleic acid sequences and proteins derived entirely from multicellular organisms (e.g. medaka fish Tol 2 transposable elements system)

[ ]  Zinc finger nucleases (ZFN) or CRISPR-Cas9 systems

[ ]  Plasmids that meet the following criteria:

* deliberately designed and constructed for the purpose of protein expression and cloning;
* non-conjugative (non F-Plasmids) and non-integrative;
* do not contain complete open reading frames derived from any microorganism or infectious agent which encodes for any of the following factors:
* regions able to complement the conjugation defect in a non-conjugative plasmid
* regions known to correspond to autonomous genetic elements in any microorganism
* regions known to contain complete “pathogenicity islands” or bacterial virulence factors excluding antimicrobial resistance genes used to facilitate selection and replication factors.

[ ]  Other – please specify details below

1. **Have the cell line/s been modified using nucleic acid derived from and/or associated with, or homologous to multicellular organisms?**

[ ]  Yes – please provide details below.

[ ]  No – go to question 11.

1. **H****ave the cell line/s been modified using nucleic acid derived from and/or associated with, or homologous to the following?**
* [Pathogens of animal biosecurity concern for biological products](https://www.awe.gov.au/biosecurity-trade/policy/legislation/pathogens-of-biosecurity-concern#pathogens-of-highest-animal-biosecurity-concern) (excluding Vesicular stomatitis virus G protein [VSV-G]), as published on the Department of Agriculture, Fisheries and Forestry's website.
* [Disease agents causing Listed Human Diseases](https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-biosec-list-diseases.htm), as published on the Department of Health and Aged Care's website and listed under the *Biosecurity (Listed Human Diseases) Determination 2016*.
* Poliovirus.
* Monkeypox virus.
* Prion proteins (whether protease resistant or not, including PRNP, PrPc, PrPsc) or any other agent of transmissible spongiform encephalopathy from any species.
* The whole genome or whole autonomous genomic region\* of any microorganism or infectious agent.

\**Autonomous genomic regions are distinct nucleic acid sequences which can be replicated independently such as transposons, entire viral genomes, entire segments of a segmented viral genome, and natural plasmids.*

[ ]  Yes – please provide details in the table below.

[ ]  No – go to question 12.

| **Name of the microorganism/s or infectious agent/s (genus and species)** | **Details of insert, including:*** **gene name, and**
* **is the insert a full gene or partial gene**
 | **Is the insert stably integrated into the genome of the cell line?** | **Will the cell line be used to:*** **culture and isolate the microorganism or infectious agent?**
* **Synthesise replication competent homologues of the microorganism or infectious agent?**
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| --- | --- | --- | --- |
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1. **Have the cell line/s been modified using nucleic acid derived from and/or associated with, or homologous to microorganisms or infectious agents other than those listed in question 10 above?**

[ ]  Yes – please provide details below.

[ ]  No – go to question 13.

| **Name of the microorganism/s or infectious agent/s (genus and species) nucleic acid is derived from** | **Is the insert stably integrated into the genome of the cell line?** | **Will the cell line be used to:*** **culture and isolate the microorganism or infectious agent?**
* **Synthesise replication competent homologues of the microorganism or infectious agent?**
 |
| --- | --- | --- |
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## Section D: Manufacturing/processing information (delete if not applicable to commodity)

Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law. Protected information collected by the department will only be used or disclosed as authorised under the *Biosecurity Act 2015*. With this in mind, manufacturers may prefer to provide information directly to the department.

1. **Provide the details of all animal material used in the maintenance of the cell line:**

| **Species of origin** | **Country of origin** | **Tissue of origin** |
| --- | --- | --- |
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**Section D: Declaration**

**This section is to be completed by the signee named in** [**section B**](#_Section_B:_Contact) **of this form.**

It is a criminal offence under Division 136 of the *Criminal Code Act 1995* to knowingly give false or misleading information to a Commonwealth officer exercising powers under Commonwealth law. This offence carries a potential penalty of 12 months’ imprisonment.

I declare that the information in this form is true and accurate to the best of my knowledge. I understand that giving false or misleading information is a serious offence.

If I become aware that the information I have provided is incomplete or incorrect, I will notify the Department of Agriculture, Fisheries and Forestry as soon as practicable.

If the department issues an import permit for products referred to in this form, I declare that the products exported to Australia will comply with all conditions on that import permit.

If manufacturing processes change so that products are no longer compliant with all conditions on the import permit, I will provide details of the change to the Australian importer so that a new application for an import permit (or an application to amend the current import permit) can be submitted to the department.

I have read and understood the privacy notice and [Privacy Policy](https://www.awe.gov.au/about/commitment/privacy) and the commercial-in-confidence notice.

**Signature (type or sign your name)**

**Full name**

**Date (dd/mm/yyyy)**

**Section F: Privacy notice**

Personal information means any information or opinion about an identified, or reasonably identifiable, individual. Personal information that is collected under or in accordance with the *Biosecurity Act 2015* is also ‘protected information’ under the Biosecurity Act.

The Department of Agriculture, Fisheries and Forestry is authorised under the Biosecurity Act to collect your personal information for the purposes of determining import conditions for your veterinary therapeutic products and for other related purposes. If you fail to provide some or all of the relevant personal information requested in this form, the department may be unable to process the import permit application that relates to this form.

Information collected by the department will only be used or disclosed under the Biosecurity Act. The department may disclose your personal information to the Department of Health and Aged Care and the Department of Climate Change, Energy, the Environment and Water, and other Australian Government agencies, persons or organisations where necessary for these purpose. It will not usually be disclosed overseas. It will only be disclosed if authorised under the Biosecurity Act.

See our [Privacy Policy](https://www.awe.gov.au/about/commitment/privacy) to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933 (or +61 3 8318 6700 outside Australia).

**Section G: Commercial-in-confidence notice**

Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law.