**Production questionnaire: Human fluids and tissues**

**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 human fluids and tissues into Australia, including:   * Human fluids and tissues not known to be infected. * Human fluids and tissues (including antisera) known to be or potentially infected with, or raised against, a disease agent. | | |
| **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 processed 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 processes 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 pen  Print in BLOCK LETTERS  Mark boxes with a tick þ or a cross ý  Attach 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 Team  Department of Agriculture, Fisheries and Forestry GPO Box 858  Canberra ACT 2601  Email [Imports@aff.gov.au](mailto:Imports@aff.gov.au) |
| **More information** | | Phone 1800 900 090 (within Australia) +61 3 8318 6700 (outside Australia)  Email [Imports@aff.gov.au](mailto: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 applicable (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. **Is the product being imported in volumes of 20mL or 20g, or less per individually packaged unit?**

Yes - go to question 5.

No - what is the volume of each individually packaged unit? \_\_\_\_\_\_\_\_\_\_\_\_

### **Please provide details on the products to be imported.**

|  |  |
| --- | --- |
| **Product name** (e.g. human blood; sera; tissue; antisera) | **Fluid/Tissue type** |
|  |  |
|  |  |
|  |  |

1. **Are the fluids and/or tissues sourced from humans with clinical signs of disease that could indicate pathology attributable to a disease agent?**

Yes – please complete the table below

No – go to question 7.

|  |  |
| --- | --- |
| **Genus and species of the disease agent (if known)**  **Note:** Disease agents include, but are not limited to, a microorganism, an infectious agent, a parasite etc. | **Provide details on any clinical signs/symptoms of disease** |
|  |  |
|  |  |
|  |  |

1. **Have the fluids and/or tissues been deliberately infected with, or raised against, a disease agent(s)?**

*Note: Disease agents include, but are not limited to, a microorganism, an infectious agent, a parasite etc.*

Yes – please complete the table below.

No – go to question 8.

|  |  |
| --- | --- |
| **Genus and species of disease agent** | **Details** |
|  |  |
|  |  |
|  |  |

## Section D: Manufacturing/processing information (leave blank if not applicable to goods)

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. **Have the fluids and/or tissues been subjected to any processing or treatment? This includes, but is not limited to:**

* Heat treatments;
* pH treatments;
* Chemical inactivation;
* Purification;
* Physical processing

Yes – please complete the table below.

No

|  |  |
| --- | --- |
| **Product/sample** | **Provide details of any treatments or inactivation methods that have been applied to the product** |
|  |  |
|  |  |
|  |  |

**Section E: 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.