

# **Production questionnaire: Culture media**

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

## **Section A: General information**

#### Purpose of this form

To support an import permit application by an Australian entity or individual to import culture media into Australia:

- Culture media
- Growth media
- Cell culture media

# Who should complete this form

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.

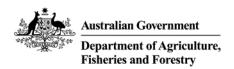
OR

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.

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#### 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 

✓ or a cross 

✓

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 <u>minimum</u> documentary and import declaration requirements policy.

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# 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

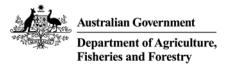
Email <a href="mailto:lmports@aff.gov.au">lmports@aff.gov.au</a>

#### More information

Phone 1800 900 090 (within Australia) +61 3 8318 6700 (outside Australia)

Email <a href="mailto:lmports@aff.gov.au">lmports@aff.gov.au</a>

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# **Section B: Contact details**

# 1. Details of authorised representative completing this form

Legal entity name			
Authorised person to sign this	Full name:		Position in company/Job title:
form (must be an employee of the			
facility)			
Select applicable option	☐ Physical manufacturer	□ Legal	manufacturer
Address			
Phone (include area code):		Fax:	
Email:			
2. Facility where products are manu	factured (if the same as question 1, write	'As abov	ve'). Include multiple facilities if required.
Legal entity name			
Address			
Phone (include area code):		Fax:	
Email:			

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3. Exporter's details (if exporter and manufacturer details are the same, write 'As above')

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

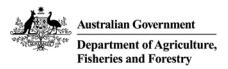
# **Section C: Product to be exported to Australia**

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

4. Please provide the names of the products, product codes and volume of each individually packaged unit.

Name of product	Product code	Volume of each individually packaged unit

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# 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*. Manufacturers may prefer to provide information directly to the department.

5. Are the products selective or differential media?						
$\square$ Yes – please provide details in the table b	elow.					
□ No						
Name of product	Selective/differential ingredient	Volume of each individually packaged unit				

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6. Please complete the following table for each product with information on the ingredients in the product.

Please complete a separate table for each product.

# **Product name:**

Ingredient	Volume (%) of each product	Origin of ingredient (animal, plant, microbial, chemical, synthetic)	Species of origin for animal derived material	Country of origin for animal derived material	Tissue/fluid of origin of ingredient for animal derived material	Processing (e.g. heat treatment, pH treatment, mechanical treatments)

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7. Please provide details of any sterilisation the final product has undergone.

Product name	Has the final product undergone heat sterilisation? Please provide the temperature (°C) and duration (minutes)	Has the final product undergone any other forms of sterilisation? Please provide information below.

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## Section E: Manufacturer's declaration

This section is to be completed by the manufacturer's representative named in section B 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.

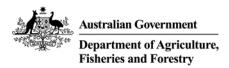
If the department issues an import permit for products referred to in this form, I declare that the products exported to Australia will comply with all conditions on that import permit.

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 and the commercial-in-confidence notice.

nature (type or sign your name)	
I name	
te (dd/mm/yyyy)	

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# **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 <u>Privacy Policy</u> 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.

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