



PRODUCTION QUESTIONNAIRE FOR THE FOLLOWING IMPORTED PRODUCTS:

- **Laboratory material / reagents**
 Including: albumins, antibiotics, enzymes, growth factors, hormones, lipids, proteins.
- **Toxins**
- **Venoms**

Questionnaire requirements:

- This questionnaire must be completed by the FINAL MANUFACTURER of the goods intended for export to Australia.
- Multiple products from the same manufacturer may be included on the one production questionnaire. Separate manufacturers must complete separate questionnaires.
- Commercial-in-confidence information should be clearly identified by the manufacturer. Questionnaires may be returned directly to the Animal and Biological Imports Branch (ABIB) to avoid disclosure of this information.
- Please use additional paper, if there is insufficient space. If providing additional documents please ensure that they are on a letterhead, dated and signed by the manufacturer.

Please consider all information provided in this questionnaire carefully. Failure to complete the questions or provide supporting documentation will result in delays in the processing of the import permit application.

1. Import Permit Application reference number (if known): _ _ _ _ _

2. Manufacturer details (establishment where the final product is made)

Name			
Address			
	City:	Country:	
	Phone:	Fax/email:	

3. Exporter details

Same as above

Name			
Address			
	City:	Country:	
	Phone:	Fax/email:	

4. Importer's Details

Name			
Address			
	City:	Country: Australia	
	Phone:	Fax/email:	

5. Provide the name, volume and intended end use of product(s) to be imported

Please list all products below or attach a list. Provide the volume of individually packaged unit to be imported. Provide end use: *in vitro* use only or *in vitro* and *in vivo* use in laboratory organisms (guinea pig, hamster, mouse, rabbit, rat or microorganism).

Product name	Volume	End use
a.		
b.		
c.		
d.		
e.		

6. List all ingredients in each product referenced in Q.5 - a separate table is required for each product
(Please list all raw ingredients below or attach a list – please include percentages adding up to 100%)

Ingredient	Composition in product (%)	Animal, plant, microbial, synthetic or chemical origin	Country and species of origin (animal derived material)

7. Are any of the ingredients derived from fermentation? (Fermentation derived ingredients can include bacteria, microbial derived enzymes, etc.)

Yes If yes, please provide details below:

No Go to Q.8

If yes, please attach a separate sheet with the following details:

- a. a list of ALL ingredients in each of the fermentation media (please indicate the origin of each ingredient (i.e. animal, plant, synthetic, etc.));
- b. country of origin for any animal derived ingredients;
- c. details of the sterilisation of the media (i.e. temperature and duration) before start of fermentation;
- d. a list of ALL microorganisms (identify down to species level) used;
- e. sourcing details of any microorganisms (i.e. culture collection, isolated from mother culture stock, drawn from a previous production batch, etc.)
- f. method of harvest for final product (i.e. direct harvest from production vats or harvest using purification/concentration procedure)

8. Please attach a manufacturing flow chart that outlines the manufacturing process for the product intended for export to Australia.

The flow chart should provide detail on the processing of raw material through to the finished product. Please include all mechanical, chemical and physical treatments and their respective measurement parameters (i.e. temperatures, pressures, durations, concentrations, pH, etc.).

9. Does the manufacturing facility have a certificate of Good Manufacturing Procedure (GMP) compliance and/or certificates of other Quality Assurance programs (e.g. ISO, HACCP)?

Yes (If yes, please attach photocopies of approval)

No

If no, please describe/provide detail on any internal QA/QC systems in place at the manufacturing facility below:

10. Other information

MANUFACTURER'S DECLARATION

I declare that the information above is true and accurate to the best of my knowledge.

Signature: _____ Date* _____/_____/_____

Printed name: _____ Position: _____

Company name: _____

Facility address: _____

Country: _____

*Must be dated within the last six months and be free from erasure and uncertified alterations. For further information on documentation requirements please refer to the [Minimum documentary and import declaration requirements policy](#)

If you have any questions or for notification of any changes in above details, please contact:

Department of Agriculture, Animal and Biological Imports Branch: Phone: **1800 900 090** or Email imports@agriculture.gov.au

See Privacy notice and General note below:

Privacy notice

Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable. 'Personal information' that is collected under or in accordance with the *Biosecurity Act 2015* is also 'protected information' under the *Biosecurity Act 2015*. The collection of protected information including personal and sensitive information by the Department of Agriculture (the department) in relation to this form is being collected under the *Biosecurity Act 2015* for the purposes of providing supporting information to assist in the assessment of the biosecurity risk related to your application to import.

If the relevant personal information requested in this form is not provided by you, the department may be unable to process your application. Information collected by the department will only be used or disclosed as authorised under the *Biosecurity Act 2015*. The personal information requested on this form may be disclosed to other Commonwealth or State Agencies. It will usually be disclosed overseas. In every case it will only be disclosed if authorised by the *Biosecurity Act 2015*.

See our [Privacy Policy](http://www.agriculture.gov.au/about/privacy) web page (<http://www.agriculture.gov.au/about/privacy>) to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933.

General note: Information provided in this questionnaire will be used to assess the biosecurity risk of goods being imported into Australia i.e. the risk of imported goods introducing a pest or disease into Australia. Based on a review of this information the Animal and Biological Imports Branch will, where possible, apply conditions to an import permit that allows the relevant product(s) to be brought into Australia.

Under Section 131 of the *Biosecurity Act 2015*, the Department of Agriculture has powers to inspect, sample, test and/or treat imported goods to mitigate biosecurity risk. These powers will be used where a Biosecurity Officer (or other authorised person) is of the opinion that imported goods may represent an unacceptable level of biosecurity risk. These powers are distinct from those related to the import permit process.

Department of Agriculture may contact overseas Government competent authorities to verify any information provided by overseas manufacturers.