

Australian Government

Department of Agriculture

PRODUCTION QUESTIONNAIRE FOR THE FOLLOWING IMPORTED PRODUCTS:

• Antibodies

- For in vitro use; and/or
- For in vivo use in laboratory organisms, i.e. guinea pig, hamster, mouse, rabbit, rat or microorganism.

Questionnaire requirements:

- This questionnaire must be completed by the FINAL MANUFACTURER of the goods intended for export to Australia.
- Commercial-in-confidence information should be marked as such by the manufacturer and the questionnaire returned directly to the Animal and Biological Imports Branch (ABIB).
- The information collected will be used to determine import conditions for these goods.
- Please use additional paper, if insufficient space.

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's Details (Please provide name and address of the facility, if different from the Manufacturer details)

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

4. Importer's Details

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

18 Marcus Clarke Street, Canberra City ACT GPO Box 858 Canberra ACT 2601 ph 1800 900 090 www.agriculture.gov.au ABN 24 113 085 695

DEPARTMENT OF AGRICULTURE

5. List the product names(s) (if applicable):

Product name	
a.	b.
С.	d.

6. Product details and end use

Name of organism the antibody was raised against	End use	

7. Product type and package size & components

E.g. polyclonal antibodies raised in a horse against <i>Clostridium tetani</i> E.g. monoclonal antibody created from a phage library & conjugated to marker X	E.g. 5mL of purified IgG – liquid suspended in phosphate buffered saline with sodium azide as a preservative

8. Provide details on how the antibody was created

Please attach or insert here (electronically) either a manufacturing flow chart or a robust description of the manufacture of this product.

Check if *commercial-in-confidence* information

E.g. against a live microorganism, inactivated microorganism, specific antigenic component, from a phage library, other. Include the following information, as applicable: animal species (including animal cell lines) used in the production; processing methods e.g. gels, blots, filters, columns etc. and purification of the final product

9.	Has any verification work been undertaken e.g. validation to confirm no viable microorganism or
	infectious agent is present

Yes (if yes provide details below)

No

10. Is there any animal material in the final product e.g. sera, albumin, supernatant fluids

Yes (if yes provide details below)

Animal material present
Species of animal
Country of origin of the animal material (and country of processing and export if different from country of origin)

Image: I

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:				
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 <u>Minimum documentary and import</u>				
declaration requirement				

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 import permit application.

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 <u>Privacy Policy</u> 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.