



**PRODUCTION QUESTIONNAIRE FOR THE FOLLOWING IMPORTED PRODUCTS:**

- **Diagnostic test kits and associated reagents, controls and calibrators.**
- **Note: Questionnaires do not have to be completed when applying for Standard import permits (see BICON for details).**

**Instructions for completion:**

- One diagnostic test kit per questionnaire.
- This questionnaire must be completed by the FINAL MANUFACTURER of the goods intended for export to Australia.
- 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.

**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. **Importer's Details**

Name		
Address		
	City:	Country: <b>Australia</b>
	Phone:	Fax/email:

**4. Identify the diagnostic test kit**

<b>Brand name &amp; product name</b> <b>Note:</b> Please list only one diagnostic test kit per questionnaire.	<b>Type of kit e.g. PCR, ELISA, SNAP, etc.</b>
<i>Example: TEST GO - Rapid Malaria Kit</i>	ELISA

**5. Does the kit test for, or contain:**

- **disease agents\*** (live, live attenuated or inactivated), or their derivatives (e.g. antigens, genetic material)
- **any components raised against a disease agent (e.g. antibodies)**

**\* Disease agents include, but are not limited to, microorganisms, parasites, viruses, prions, plasmids, and viroids.**

**Yes** – please complete the table below.

**No** – go to question 6.

<b>Name of disease agent (genus and species)</b>
<i>Example 1: Human immunodeficiency virus</i>

<b>For Nucleic Acid Amplification Kits (e.g. PCR): Are the primers, positive controls etc. each under 1000 nucleotides?</b>
<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b>

<b>For all other kits: Provide details of the inactivation of the disease agent or derivative included in the kit.</b> <b>Note:</b> Inactivation details are only required for disease agents which are exotic to Australia and generally require a physical containment level of 3 or above.
<i>NA = endemic in Australia</i>
<i>Please provide robust information regarding the recombinant technology used, methodology used to inactivate the disease agent and all validation data.</i>

6. Does the kit contain animal derived material?

Yes – Please complete the appropriate table below.

No – Go to question 7

Kits testing for HUMAN conditions			
The species and country of origin is only required for volumes greater than 20ml or 20gm (per individually packaged unit).			
Name of kit component	Volume and type of animal derived material contained in each individually packaged unit	Species of origin	Country of origin
<i>Example: Reagent D</i>	<i>15ml sera</i>	<i>NA</i>	<i>NA</i>
<i>Example: Reagent E</i>	<i>25ml sera</i>	<i>Avian</i>	<i>United Kingdom</i>

Kits testing for VETERINARY (or environmental) conditions			
For veterinary kits which do NOT test for disease agents; the species and country of origin is only required for volumes greater than 20ml or 20gm (per individually packaged unit).			
For veterinary kits which test for disease agents; the species and country of origin is required for all volumes of animal derived material. <b>Note:</b> For purified proteins e.g. bovine serum albumin (BSA), the species and country of origin is only required for volumes greater than 20ml or 20gm (per individually packaged unit).			
Name of kit component	Volume and type of animal derived material contained in each individually packaged unit	Species of origin	Country of origin
<i>Example: Reagent A</i>	<i>5ml BSA</i>	<i>NA</i>	<i>NA</i>
<i>Example: Reagent B</i>	<i>25ml BSA</i>	<i>Bovine</i>	<i>USA &amp; Canada</i>
<i>Example: Reagent C</i> <i>[For kits which do NOT test for disease agent]</i>	<i>2ml sera</i>	<i>NA</i>	<i>NA</i>
<i>Example: Reagent C</i> <i>[For kits which test for disease agent]</i>	<i>2ml sera</i>	<i>Avian</i>	<i>United Kingdom</i>

**7. Kit insert**

Please attach, or provide a web link to the kit insert.

**Note:** MSDS sheets are not useful for assessing biosecurity risks and should not be provided.

**Completion of this questionnaire is not required where the kit insert:**

- provides all of the information requested above, and
- sets out the information in a manner that is easy to assess

**If sufficient information is not provided, or the information is difficult to identify, a completed questionnaire will be requested.**

I have attached an insert, or the web link is as follows: \_\_\_\_\_

**8. Other details**

Any other information relating to the kit that may be of use to the assessment of the application

I have attached additional 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: \_\_\_\_\_  
\_\_\_\_\_

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](mailto:imports@agriculture.gov.au)

**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.