# pRODUCTION Questionnaire FOR THE FOLLOWING IMPORTED PRODUCTS:

* **Human therapeutics and medicines**
* **Bulk ingredients for manufacture into human therapeutics and medicines**

**Questionnaire requirements:**

* This questionnaire must be completed by the MANUFACTURER of the goods intended for export to Australia.
* This questionnaire should be submitted with the application for a permit to import any of the goods outlined above into Australia.
* The information collected will be used to determine import conditions for these goods.
* Please use additional paper/attachments 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.**

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| NOTE:  For importers of goods listed on the ARTG: only the product name and ARTG reference number is required on your application. You do not need to complete this questionnaire.  Importers of fully finished therapeutics, that require no further processing after import, may choose to provide product information sheets instead of this questionnaire. The product information sheet must provide details of the ingredients in the product and the use of the product. |

1. **Import Permit Application reference number** (if known)**:** \_ \_ \_ \_ \_ \_ \_
2. **Where is the product manufactured?** (Please provide name and address of the facility)

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

1. **Exporter’s Details** (if different from manufacturer)

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

1. **Importer’s Details**

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

1. **Name of product(s) to be imported** (Please list all products below or attach a list)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | a. |  | b. |  |
| c. |  | d. |  |

1. **List all ingredients in each product referenced in point 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)** |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |
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|  |  |  |  |  |

1. **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 question 8

|  |  |
| --- | --- |
|  | 1. a list of all animal ingredients in each of the fermentation media including country or origin and species of origin; 2. details of the sterilisation of the media (i.e. temperature and duration) before start of fermentation; |

1. **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, etc.).

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1. **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:

|  |  |
| --- | --- |
|  |  |

1. **In what way is the product packaged?** (Please provide details on the package size as this will impact on conditions that will be applied to the import permit)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | a. | Packaged in new packaging? | | Yes | No |
|  | b. | What form are the goods being imported in? | Fully finished for retail sale  BULK for further processing/packaging | | |
|  | c. | What is the volume of each individually packaged unit? | ……………………………….. (please specify volume in Kg or Litres) | | |

1. **Provide details of Approved Arrangements sites and TGA approved manufacturing sites**

|  |  |
| --- | --- |
|  | This question is not mandatory. However, for some bulk material import conditions may require goods to be processed in approved facilities. |

# 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This declaration must be dated within the last six months and be free from erasures and uncertified alterations. Additional information must be in the form of a manufacturer’s declaration.

For further information on documentation requirements please refer to the [Minimum documentary and import declaration requirements policy](http://www.agriculture.gov.au/import/arrival/clearance-inspection/documentary-requirements/minimum-document-requirements-policy)

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

**Department of Agriculture, Fisheries and Forestry Animal and Biological Imports Branch**:

Phone: **1800 900 090** or Email [**imports@aff.gov.au**](mailto:imports@aff.gov.au)

**See Privacy notice and General note below:**

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| **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, Fisheries and Forestry (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, Fisheries and Forestry 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, Fisheries and Forestry may contact overseas Government competent authorities to verify any information provided by overseas manufacturers. |