Desktop Audit Questionnaire – Pet Food

Manufacturers are required to provide a response against each of the items below.

Manufacturers are encouraged to provide a copy of a site master file for the manufacturing site and augment their responses below with references to the relevant section of the site master file.

1. Preliminary questions

1.1 Have Australian biosecurity officers (or third-party auditors auditing on behalf of an Australian importer) previously audited the manufacturing site?

Yes (continue to question 1.2)

No (continue to section 2)

1.2 Have any of the following changes been made at the manufacturing site since this last audit?

- Changes to infrastructure at the manufacturing site that impact production lines
- Changes to company ownership at the manufacturing site
- Changes to the status of quality management at the manufacturing site

Yes – Provide more information on the change below:

_____
_____
_____
_____

No (continue to section 2)

2. General information requirements

2.1 Name and address of importer

Name of contact person:

2.2 Name and address of exporter

Name of contact person:

2.3 Name and address of manufacturing facility

Name of contact person:

Phone:

2.4 Provide an organisation chart for key personnel at manufacturing facility.

2.5 Number of days worked per week

2.6 Number of shifts worked per day

2.7 Number of employees

2.8 Number of production lines

3. Facility / Staffing

3.1 Provide a description/map of the layout of the buildings on the manufacturing site such that the designation and conditions of use of all rooms are correctly identified as well as the materials handled within them.

3.2 Provide a description of the facility's security, including how authorised personnel are identified and enter/exit the facility.

3.3 Describe the process for ensuring that only appropriate personnel have access to production and restricted areas and how this is monitored.

3.4 Provide details of staff training procedures including induction and ongoing / refresher training and any validation procedures to be deemed proficient.

4. Production

A complete response to the items listed below will include reference to the facility site maps or other site plans.

4.1 Provide names and type of all products manufactured at the facility for export to Australia.

4.2 Provide names and type of all products manufactured at the facility NOT for export to Australia.

4.3 Are there dedicated production lines and or equipment used for the preparation and manufacture of product destined for Australia, if yes please provide details?

4.4 Provide a description of any cleaning / sanitation processes used on the equipment between batches of Australian destined and other product.

4.5 Provide a full description of the supply chain for the goods exported to Australia, including the details of off-site storage warehouses for raw materials, intermediate, and finished product.

4.6 Provide information for the process of receiving and storing ingredients, including systems for monitoring, and recording receipt of raw materials.

4.7 Provide a broad description of each stage of the manufacturing process for product manufactured for export to Australia from receipt to final load out, including any heat treatments and equipment used, at each stage of production.

4.8 Describe the process to deal with non-conforming product, both final product and initial ingredients.

4.9 Describe processes and systems in place for managing the risk of cross contamination during production. Manufacturers should reference all relevant factors including:

- Cleaning and sterilisation of equipment, laboratories, and production lines
- Maintenance of employee hygiene
- Trafficking restrictions for equipment and personnel
- The use of equipment or areas within the manufacturing plant that are dedicated to production of specific products
- Restrictions on the order of production of different products

4.10 Describe procedures to prevent cross contamination in storage/warehousing areas. How are warehouses designed and organised to manage the storage and movement of raw materials, packaging/labelling materials, intermediate/finished product?

4.11 Describe how product flow and personnel movement are designed to minimise risk of cross contamination during production.

4.12 Describe how storage areas are restricted to authorised personnel only and how entry/egress is monitored.

4.13 Describe procedures that are in place for general hygiene requirements for staff entering and exiting the plant.

4.14 Describe procedures for plant sanitation and cleaning of equipment.

4.15 Describe procedures for sanitation requirements for any personal equipment (e.g. aprons, scabbards, knives) used by staff.

4.16 Describe the system designed to prevent contamination through vermin/pest infestation.

5. Materials of biological origin.

5.1 Describe how the quality management system ensures separation of materials of animal origin and manages the risk of cross contamination.

5.2 Describe the systems and processes designed to identify, separate, trace and monitor consumption of materials of animal origin. Include detailed information relevant to the traceability and identification system for raw materials used in manufacture through sourcing, manufacture, and dispatch of final product.

5.3 Describe the traceability and identification system from sourcing of raw materials for manufacturing and dispatch of final product. Outline how a clear audit trail is maintained from the original supplier of raw materials to final quality release and dispatch of finished product?

5.4 Provide a list of all materials of animal, plant and microbial origin that are held at the facility by completing the following tables (whether they are manufactured at the facility or not).

For materials of animal origin please include information on the supplier and country of origin of the animals from which the material is sourced.

Table 1. Ingredients of animal used in products manufactured for export to Australia. Please include coatings (i.e. flavour enhancer) used on the final product.

Ingredient	Species	Country of Origin	Supplier

Table 2. Ingredients of animal origin held in plant but NOT used in products manufactured for export to Australia.

Ingredient	Species	Country of Origin	Supplier

Table 3. Summary of all ingredients of plant origin held in plant.

Ingredient	Species	Supplier

Table 4. Summary of all ingredients of microbial origin held in plant.

Ingredient	Species	Supplier

6. Heat treatment

6.1 What is the minimum **CORE** temperature and time used for processing all animal derived ingredients used in product manufactured for export to Australia? Provide a summary in Table 5.

6.2 List all heat treatment equipment used in the manufacture of products for export to Australia.

6.3 Are appropriate records kept ensuring minimum heat treatment was reached for each batch? Supply an example of one of these records kept during manufacture of product for export to Australia.

6.4 Is the heat treatment equipment fitted with an alarm system? Describe what happens if the minimum temperature is not reached?

6.5 Describe the process if the product does not meet minimum heat requirements.

6.6 Describe the repair and maintenance operating procedures kept for all the heat treatment equipment including servicing schedule for all equipment listed in response to Question 6.2.

6.7 Are the temperature sensors/probes in the heat treatment equipment calibrated to ensure accurate readings? If yes, what is the frequency of calibration? By whom is the calibration done?

Table 5. Heat treatments applied to ingredients of animal origin in products manufactured for export to Australia.

Ingredient	Heat Treatment		Facility where treatment applied
	Min core temp	Time at core temp	

7. Quality assurance, quality control

7.1 Provide a detailed description of the company system for quality assurance. The response should reference the procedure for accrediting new suppliers and the ongoing management of all supplier data.

The response should:
- clearly demonstrate how commercial and regulatory specifications are maintained.
- address the continual identification and traceability of raw materials against specifications.

7.2 Describe the elements of quality control that are built into the system to ensure product is manufactured to meet company and client specifications and the requirements of regulatory agencies. Include the frequency of product quality review.

7.3 Explain the system for company review of the quality management system. How does this review process feed into ongoing process improvement?

The response should reference all relevant internal review processes including internal audits, senior management reviews, periodic product reviews, mock product recalls, traceability exercises and the complaints review process.

7.4 Describe the system for change control. This system ensures that a formal evaluation and impact assessment is done before changes, which affect production, quality, and/or regulatory compliance, are implemented.

The response should explain the procedure for responding to changes that impact information supplied in support of an import permit application.

7.5 Provide details of current regulatory authority approvals for the facility. Provide copies of certificates of approval/registration. How often is the facility subject to audit by the regulatory authority?

7.6 Provide the dates of the most recent audits/inspections carried out by the regulatory authority including significant outcomes that may be an issue to biosecurity risk.

8. Documentation

8.1 Provide details of the company's document control system within the manufacturing facility. How does the document control system ensure all documents are accurate and up to date?

8.2 Are approved and dated specifications available for all products, including raw materials, packaging/labelling materials?

8.3 Describe the process for creation of new specifications for raw materials that have been qualified and approved for use in manufacture. Explain how the system ensures established specifications are reviewed for content accuracy.

8.4 Describe the process for creation of new documents, including standard operating procedures (SOPs). Who is responsible for identifying the need for new documents? Who creates the document and what is the process for approval of new documents?

8.5 Describe the system for review of documents, including SOPs. How often are documents reviewed and who is responsible for the review?

8.6 Describe the procedure to be followed to update a SOP?

8.7 Describe how employees are made aware of the release of new documentation/SOPs? How does the facility ensure employees incorporate new processes, outlined in new or amended documents, into their work program?

8.8 Describe how are rescinded documents removed from the document control system?

8.9 How long are batch/serial specific records kept after the expiry date of final products?

8.10 Are Australia's requirements for labelling, if any, documented?

8.11 Provide a list of all current SOPs in use within the facility by completing Table 5.

8.12 Provide copies of the SOPs that describe the following:

- Maintenance/repair program for manufacturing operations i.e., planned and unplanned maintenance events
- Pest control program
- Employee hygiene programs
- Sanitation and cleaning of production suites
- Cleaning of production equipment
- Receipt into the facility of all starting materials for use in production, including packaging materials
- Labelling and storage of starting materials
- Quarantine storage procedure for incoming raw materials, particularly animal derived materials
- Release procedure for raw materials to be used in production
- Sampling procedures for raw materials, intermediate and final product
- QA rejection of raw materials, intermediate and final product
- Quarantine procedure for final product pending final QA release
- QA release of final product for commercial distribution
- Batch traceability for product recall purposes

Table 5 Summary of SOP's held by the facility, please highlight those used in manufacture of products for export to Australia.

SOP #	SOP title

9. Certification

9.1 Who is responsible for verifying compliance in relation to sourcing and thermal processing?

9.2 Who is responsible for issuing Manufacturer's declarations?

9.3 Describe the process for obtaining government certification from the relevant government authority to accompany import consignments and who is responsible?

10. QA Manager's declaration

I declare that the information provided in this document and in supporting dossiers is accurate and that the Department of Agriculture, Fisheries and Forestry will be notified of any changes to the production process which affect the content of these documents.	
Signature:	
Name:	
Date:	
Position:	
Company name and address:	

11. Fees for desktop audits

The below costs are given as a guide only and are subject to variation.

Category	Description	Unit	Cost per unit
Audit – in office	Desktop audit of production manuals etc.	¼ hour (or part thereof)	$ 37.00 (AUD)