Australian Government
Department of Agriculture, Fisheries and Forestry

Approved Arrangement Checklist – Dairy Manufacturing Establishment

Use this checklist to review your food safety system and assess your preparedness for audit for compliance with the requirements of the Export Control Act 2020 and the Export Control (Milk and Milk Products) Rules 2021

Company name:	Completed by:	Position within company:	Date:
Physical address of establishment			
Products/ manufacturing processes you want to be export registered for. Please tick all relevant operations.	☐ Pasteurising of liquid milk (white/ flavours/full cream/skim ☐ Pasteurising of cream ☐ Thermalising/ standardising milk &/or cream ☐ ESL milk ☐ ESL cream ☐ UHT milk ☐ UHT cream ☐ Yoghurt manufacturing (**≤** 4.5 pH) ☐ Dairy dessert manufacturing (> 4.5 pH) ☐ Ice cream ☐ Butter ☐ Hard &/or very hard cheese	☐ Blending & packing of milk powders ☐ Spray drying of powders ☐ Infant formula ☐ Freeze drying ☐ Lactoferrin ☐ HPP ☐ EU composite dairy products ☐ AMF ☐ Ultra filtration ☐ Processed cheese ☐ Soft cheese ☐ Other. Please specify_____	
Countries you want to export to once approved			

Requirements of export registration approval

- Company must provide pre-audit documents for review and acceptance by the Department prior to the initial registration audit is undertaken. Refer to the document "Guide to Requirements in Becoming Registered Export Dairy Manufacturer".
- Company must meet compliance against each of the audit elements.
- Physical location of premises must be inspected for fit for use, cleanliness and good repair.
- Manufacturing of milk products that the company is seeking export approval must be observed sufficiently.
- Once the auditor has assessed that the HACCP plan/s element is compliant, a copy of the establishment's site plan must be supplied to the Department as part of the approval process.
- Once the auditor has assessed the site element as compliant, a copy of the establishment's HACCP plan must be supplied to the Department as part of the approval process.

Approved arrangement checklist

The following checklist is designed to assist you in your self-assessment review to see if you are ready for the initial audit in seeking to becoming an export registered dairy manufacturing establishment.

The Approved Arrangement relates to your company's responsibilities in meeting export requirements as the manufacturer of dairy products that can be exported. If you contract manufacture or do not directly export, it does not void your responsibilities in meeting the requirements listed below. For example, if you contract manufacture (including packing of product), the requirements of ensuring having export trade descriptions and product testing to mention a few elements is still the responsibility of your company.

To help achieve a successful compliant outcome for each audit element where documented procedures are required, it is important to detail responsibilities, what and how it is to be done and where necessary records are made. The procedures must also identify how the company takes corrective actions and verification.

Notes:

- It is not acceptable to respond with just 'yes' or 'no' responses, a full response is required.
- Please do not include attachments. Your documents may be reviewed as part of the audit process.

Legislation Legend: Export Control (Milk & Milk Products) Rules 2021 as C = Chapter, P = Part, D = Division, S = Section

Checklist Contents – Elements of the arrangement

1. Management practices
2. Internal audits, corrective actions
3. Plans and specifications
4. Cleaning
5. Water sampling
6. Pest control
7. Protection, Segregation, Waste and other products
8. Protective clothing, premise construction, hygiene and GMP/GHP
9. HACCP
10. Sampling/ testing
11. Training
12. Identification, traceability and recall
13. Approved supplier, ingredients and packaging
14. Receiving and dispatching
15. Transfer and Manufacturer declarations of compliance
16. Importing country requirements
17. Loading of sea and air freight containers
18. Department applied seals
19. Pasteurisation and other heat treatment processes
20. Trade descriptions
21. Maintenance and calibration

1.Management practices, commitment to food safety and records			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
1.1 Have **management practices** been documented to include: • The organisational structure? • Roles & responsibilities of staff at the establishment? • Duty statements for key staff? • Is there a management review process in place that ensures all elements of the Approved Arrangement are reviewed on an annual basis? How is it addressed? (eg. Management review meetings)	C5 P1 & P2 S5-2 S5-37 S5-38 S5-40		Management review is to cover all elements including importing country requirements, operational hygiene, product standards, corrective actions, structural requirements, trade descriptions, internal audits and review of monitoring records. Management review will check that verification activities that have been put in place are being carried out effectively.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element. Please do not include attachments. It is not acceptable to respond with just "Yes" or "No" responses.			

1.2 Has the **management's commitment** been documented? Does it include: • A commitment to food safety including provision of resources? • Compliance to meeting importing country requirements? • Compliance in meeting the requirements of the Rules and Act?	C5 P1 & P2 S5-2 S5-37		As a minimum, a statement committing to meeting compliance with the export legislation of the Export Control 2020 and Export Control (Milk and Milk Products) Rules 2021.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
1.3 Are there documented procedures available specifying: • All records or documents made and received by the occupier relevant to meeting the requirements of the legislation are **retained** for not less than 3 years? • All **variations** made to the Approved Arrangement are recorded when made and that where the variation to the Approved Arrangement has the potential to adversely affect compliance with the Rules or the fitness for purpose of the food, the variation is not implemented unless the variation is approved in writing by the Department?	C11 P2 C5 P4 D1		It is expected that the occupier will have systems in place that ensure that: • Each document made by the occupier or comes in possession of the occupier that is relevant to the occupier complying with the Act, the Rules, the Approved Arrangement or a condition of the Arrangement, are retained for a minimum of 3 years. • Variations to the documented Approved Arrangement are identified in a register or "like" system that details all changes made to the Approved Arrangement and where applicable, pre-approvals, new processes, exemptions, ect.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

2. Internal Audits and Corrective Actions			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
2.1 Is there a procedure in place for conducting **internal audits**? Does the procedure include the frequency of audit and that all the elements that are audited within a 12 month period? Does the internal audit cover all aspects of the establishment and its operations as well as the Approved Arrangement including but not limited to: • Export documentation • HACCP • Good manufacturing/hygiene practices • Maintenance including equipment/ premises being in good repair • Transport • Training • Trade Descriptions • Structural • Cleaning	C5 P2 S5-40		It is an expectation that the company has a documented internal audit program in place that covers all elements of the Approved Arrangement scheduled to occur at least yearly and that: • Results of internal audits are documented, including details of any actions required to address non-compliances identified, when the corrective action to be taken and how actions have been assessed as effective. • Evidence is gathered to support how the outcome of the internal audit was determined. The reviewing of procedures, records and through observations are all tools of gathering evidence to show compliance or not. Internal audits must be conducted specifically for the establishment to which the Approved Arrangement is applicable and that other third party or regulatory audits cannot be used in place of an internal audit.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
2.2 Is there a procedure for documenting **corrective actions** where monitoring, verification, internal audit, or an audit undertaken by a third party identifies a non-compliance? Does the procedure include actions to: • Investigate the cause of the non-compliance? • Describes how the non-compliance is to be addressed? • Determine the timeframe for action to be completed by? • Prevent recurrence? • Assess effectiveness? • Allocate responsibility for management and action?	C5 P2 S5-39 S5-40		At audit, your system will be reviewed to verify that the corrective action procedure is in place and being followed. Expect the auditor will: • Review a sample of non-compliances identified and sight records/ documents associated to support actions undertaken. • Check that the sample of non-compliances reviewed are closed or are being managed by the company. • Review closed non-compliances to determine if action taken has been verified as effective.

• Escalate when corrective action is not done within the allocated timeframe? • Have a system covered for addressing corrective action needed to be taken for external audits (eg Commonwealth regulator; state regulator)?			• Review a list of corrective action reports as evidence that the process is up to date and includes all internal and external audit results. Note – when assessing corrective action against effective timeframes, the severity of consequences and likelihood of the risk should be considered. An immediate or short term corrective action control might need to support addressing the non-compliance.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

3. Plans and Specification			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
3.1 Are **plans of the establishment** available, accurate, legible and includes: • The layout and floor plan of the structure. • The floor plan shows the different areas of the premises (eg production zones, storage, receival and dispatch). • The plan includes all levels (including mezzanine and office-only levels). • The floor plan shows the key equipment (eg pasteurisers, tanks, fillers). • The water supply, stormwater and waste water drainage (including drain locations and sewer lines).	C4 P1 D1 S4-4		Plans are required to be available and accurate and will be assessed by the auditor. A copy of the floor plan showing the different production/ storage areas and key equipment will be required to be supplied to the auditor as part of the approval process. Auditor will verify floor plan during initial registration onsite audit.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

4. Cleaning and Sanitising including CIP (Cleaning in Place)			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
4.1 Is there a documented **cleaning program** in place? Is it accurate, does it cover all relevant areas and equipment including storage areas, is it suitable and does it match what is occurring?	C5 P1 S5-4 C5 P2 S5-9		It is expected that there is a fully documented cleaning and sanitation program in place. This includes: • Work instructions for specific equipment/ areas describing the chemicals to be used, concentrations, application and sequence of cleaning. • Records available for the auditor to ensure that documented cleaning program is conducted in accordance with stated frequencies and stated objectives. • Key personnel may be interviewed and questioned on their knowledge, training, understanding of procedures and HACCP requirements where applicable. Note – where an external party is used to clean the premises, controls of how cleaning is undertaken and verified must still be covered.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
4.2 What systems are in place to support that **cleaning (non-CIP)** is documented and effective: • Are cleaning checklists and other similar records made from visual inspections and checks that are undertaken? • Is internal audits of GMP and training part of the program?	C4 P1 S4-7 C5 P1 S5-4 C5 P2 S5-9		It is expected that internal audit records, daily cleaning records and GMP records are in place for cleaning and hygiene programs to show that these programs are being implemented effectively. Ensure that verification of cleaning includes evidence of sanitation of heat treatment equipment, titration checks for effectiveness of chemical strengths, ect. Ensure that premises and equipment used to produce food is clean.

Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
4.3 If applicable, the company has an **environmental monitoring** program in place, does it include: • What type of indicator/ microorganism testing is occurring? • Limits defined for testing? • Frequency and locations of sampling defined? • Records to be made? • Corrective actions and possible notifications?	C4 P1 S4-7 C5 P1 S5-4 C5 P2 S5-9		At audit, environmental monitoring test records including laboratory records of pathogens such as Listeria will be sighted and checked against procedures.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
4.4 If applicable, what documented systems are in place to support the **CIP cleaning** is effective: • What types of washes undertaken (ie caustic Vs caustic/ acid) and their frequencies? • Defined monitoring controls including the concentration and amount of chemical required? • Verification including testing to ensure no residual chemicals remain? For example, flushing of system. • What records are made? • Corrective actions? • Validations have been completed for each type of CIP cleaning and for each CIP circuit/ set?	C4 P1 S4-7 C5 P1 S5-4 C5 P2 S5-9		Check that set up procedures are available and are being followed. Supporting CIP records to demonstrate cleaning is effective and that no chemical residues remain. System is included in the maintenance program. CIP validation must be supported with an executive summary describing the CIP circuit, chemical type (caustic and caustic/acid), flow rate, ect as well as supporting evidence demonstrating that the CIP is effective. Data from activities such as conductivity or swabbing could be used to show this.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

5. Water Sampling			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
5.1 Are there procedures in place for ensuring **water is potable** and does not contain Ecoli? Documented program to include: • Water is tested for no detection of E.coli for every 100 millilitres. • Water is tested for E.coli monthly. • The location (water outlets) of sampling is identified and where necessary, have a rotation plan in place for the sampling of those locations. • Procedures in place on how the collection of water samples are undertaken. • Testing of water samples undertaken in a NATA accredited laboratory. • When corrective actions are triggered and what controls are implemented due to a failed water test result.	C4 P1 S4-9 C5 P1 & P2 S5-4 S5-11		It is expected that the documented program clearly identifies responsibilities of people for the management of the program as well as those staff who may undertake tasks (eg samplers). As part of the program, the establishment will need to demonstrate the location of water sampling points and where necessary, a rotation to ensure that all relevant points are covered off. A water map showing the location of each water sampling point and a table showing rotation of these throughout a year are examples of documents that might be used to demonstrate this within the documented program.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
5.2 Procedure needs to define what **chemical/ physical limits** are used to ensure that the water is potable?	C4 P1 S4-9 C5 P1 S5-4		If the water is sourced from the local water authority, a copy of the annual testing results must be obtained. If the water comes does not come from a town water supply (eg. Bores, rivers, rainwater), the company must undertake chemical/ physical testing as per the Australian Drinking Water Guidelines.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

5.3 Is there any use of **non-potable water and/ or recycled water** used at the establishment? Is so, then it must be identified within the Approved Arrangement and include under what circumstances the water is used for and what controls are in place.	C4 P1 S4-9 C5 P1 S5-4		The use of non-potable and/ or recycled water must have undergone a risk assessment that is documented and covered by appropriate procedures. Risk assessment to detail the source and nature of the water and in what circumstances it can be used.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

6. Pest Control			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
6.1 Is there a documented **pest control** program in place and what systems are in place to support that the program is effective (eg records, reports, verification, GMP audits, pest register).	C5 P2 S5-9		There is an expectation at audit that: • Pest control reports are available and complete. • Recommendations from the reports are being acted upon. • The chemicals and baits being used are as per the documented program. • Bait stations are accessible and in accordance with location map. • A pest sighting register or similar record is in place and is being used by staff and pest controller.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

7. Protection, Segregation, Waste and Other Products			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
7.1 Is there a documented system in place that ensures that hazardous materials (eg **hazardous substances, chemicals, inedible product, allergens, waste and non-conforming product**) are adequately stored and identified to prevent cross contamination? Procedures for the identification and controls of hazardous materials must be in place.	C4 P1 D1 S4-9 C5 P1 & P2 S5-4 & includes S5-9 & S5-11		The aim is prevention of cross contamination of dairy products. Chemicals are to be stored appropriately with suitable segregation and identification. Waste, inedible material and hazardous substances are to be separated and identified. Allergens to be identified in the Approved Arrangement and procedures and risk assessments identifying hazards and controls should be described. Inedible product and non-conforming product controls to be identified and segregated.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
7.2 Where applicable, are there procedures in place to ensure product is not contaminated through the use of : • **Steam?** • **Compressed air?** • **Other gasses**?	C4 P1 D1 S4-9 C5 P2 S5-11		Examples of controls includes: • Identification of boiler chemicals used to ensure steam is of culinary quality. • Air filtering systems and drains are in place (where applicable). • Risk analysis undertaken on other gasses used. Note – the use of steam, compressed air and other gasses that could be present as a contamination risk may not be directly related to the food manufacturing processes itself and might include cleaning that is used for food manufacturing areas and equipment.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

7.3 Are there documented programs in place where **other products** that are being manufactured or stored at the establishment that are not export eligible such as: • Domestic milk and milk products? • Animal food (stock food)? • Manufacturing grade milk and milk products? • Products not fit for human consumption? • Products other than milk and milk products?	C5 P2 S5-25 S5-32 S5-33 S5-34		Documented programs are in place for non-export eligible products to ensure that they are identified, stored correctly and labelled correctly. Assessment of potential risks (eg HACCP) needs to be considered and the manufacturing of domestic milk and milk products, animal food and manufacturing grad milk and milk products at the establishment. Where product has been identified as not fit for human consumption or downgraded and it is not disposed of, there must be a documented system in place for its management and labelling. Where product is of manufacturing grade and is export eligible and can be exported, a documented system must be in place to ensure that it is identified sufficiently.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

8. Protective Clothing, Premises Construction, Personnel Hygiene and Good Manufacturing Practices/ Good Hygiene Practices			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
8.1 Are there documented procedures in place to ensure that **protective clothing** and footwear at the establishment is: • Protective clothing must be worn in only areas suitable for purpose and not pose as a risk of contamination? • Maintained in good repair? Clean and sanitary? Stored appropriately? • Is worn in all food handling areas? • Includes both staff and visitors?	C4 P1 S4-8 C5 P2 S5-12		Examples of controls includes: • Uniforms are stored and protected. • Adequate facilities for staff clothing storage. • Amenities are clean and hygienic. • Protective clothing is covered by staff induction and training.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
8.2 Are there documented procedures in place at the establishment that ensures the **personal hygiene** of staff in food handling areas meet the requirements of the Rules? Do these procedures include: • Storage of personal items? • Sickness and medical conditions? • Contamination from jewellery, clothing, behaviours, ect? • Hand washing with warm water? • Sanitising?	C5 P2 D3 S5-12		It is expected the auditor may: • Verify records are checked and verified to demonstrate that staff are trained in all aspects of food safety, including procedures. • Interview various staff at random to gauge knowledge of person hygiene program (including notification of diseases, ect). • Observe staff are complaint with jewellery policies, requirement for hair coverings ect. • Observe that hand wash facilities are supplied with warm water, soap and hand drying equipment and located in suitable areas for food handling staff to use.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

8.3 Are checks in place to ensure: • Staff are complying with documented procedures and wearing suitable protective clothing and observing good hygienic and manufacturing practices? • Are all areas of the premises and surrounds including storage areas, included in the company's internal audit audit/ GMP and housekeeping systems including pre-operational checks prior to production.	C5 P2 D3		It is an expectation that documented procedures and checks are in place and that records are kept demonstrating staff are following documented procedures and the establishment equipment used to manufacture milk and milk products is maintained to a standard of cleanliness and good repair. There is an expectation that: • Premises and equipment maintained to a suitable state of cleanliness that ensures there is no accumulation of rubbish, food waste, dirt, dust or other foreign matter. • Premises and equipment in a good state of repair to allow for safe food manufacturing.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
8.4 **Construction of premises and equipment** must: • Facilitate the preparation of milk and milk products for export as food fit for human consumption and be fit for purpose for which they are used. • The fixtures, fittings and equipment are constructed so that it does not cause contamination of milk and milk products. • Food contact surfaces and storage devices are constructed so that they can be cleaned and sanitised and not cause contamination of milk and milk products.	C4 P1 D1		The auditor will observe that: • Structure of the premises is sound and excludes the entry of dirt, dust, other foreign matter, fumes and other contaminates. • Structure of the premises does not permit the entry of pests and does not facilitate the harbourage of pests. • Walls and ceilings are smooth and impervious and able to be effectively cleaned and sanitised and excludes the entry of dirt, dust, other foreign matter, fumes and other contaminates. • Floors are smooth and impervious and able to be effectively cleaned and sanitised when necessary to do so.

			• The immediate surrounds of the premises are adequately drained and minimise the risk of dust, pests and contaminants entering food handling areas. • Food contact surfaces, fixtures, fittings and equipment are fit for purpose, doe not pose a contamination risk to the food being prepared and are smooth and impervious and can be easily cleaned and sanitised. • Hand wash facilities are located in or adjacent to food handling areas.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

9. HACCP			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
9.1 Does the company have a documented **HACCP** program in place and is the program supported by: • Product descriptions of each process line (to be approved for export operations). • Methodology of risk identification including risk assessment tool (eg risk matrix, decision trees) in place. • Purpose and scope as well as HACCP team defined. • Flow chart diagrams that are accurate of the process and all inputs for each export process line. • Accurate and complete risk assessment (eg hazard analysis) for each export process line. • Accurate and complete HACCP Audit Tables that includes the identification of critical limits, responsibility, monitoring of control measures and corrective actions of CCPs.	C5 P1 S5-2		The establishment is required to provide a copy of the HACCP plan/s for each export process line to the auditor as part of the approval process. At audit, it is expected that the establishment can provide complete HACCP plans for each export process line that want approved. The auditor will: • Confirm each different process line has an associated HACCP program. • Confirm each HACCP program has been reviewed at least on an annual basis and that has been verified. • Review the HACCP plan including its product descriptions, flow charts, risk assessment and HACCP tables for

• Verification of HACCP that includes HACCP review and internal audits. • Training of key staff. • Validation of significant hazards including CCPs. • Notifications of significant HACCP variations (eg new processes, new/ different processing equipment or methods) must be provided to your export regulatory auditor and be approved in writing by the Department before they are implemented. • Procedures that detail monitoring controls and corrective actions for hazards including CCPs.			completeness and accuracy. If multiple HACCP plans, at least 2 plans could be assessed. • Verify process steps from the HACCP plan by observing manufacturing of the milk and milk products involved. • Verify HACCP controls are being implemented by observing manufacturing of milk and milk products involved. • Review a random selection of CCP records and CP records. • Review a selection of CCP training records for staff involved in HACCP monitoring and management. • Validation evidence for CCPs reviewed. Validation evidence can include a validation/justification table as part of the HACCP plan but also include separate documents including an executive summary and supporting data. • Review procedures for the monitoring of significant hazards including CCPs.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

9.2 **Manufacturing/ production operations and methods** are following documented HACCP plans and supporting processing procedures. The establishment must be manufacturing milk products under the HACCP plan it wants to be export registered for as part of the export registration onsite audit. A full commercial production run is not required but there must be sufficient manufacturing to allow for an assessment that HACCP controls are being implemented by the establishment.	C5 P1 S5-2		The auditor will observe production operations for all milk and milk products to be approved for export and will verify: • Production methods align with the relevant HACCP plan. • Production flow is accurate and aligns with the HACCP plan (eg process steps from flow chart and hazard analysis). • Inputs are accurate and align with the HACCP plan. • Raw materials and ingredients are identified and store appropriately. • Monitoring of CCPs and significant CP hazards takes place and relevant accurate records are made. • Products are protected from the likelihood of contamination and temperature abuse (where applicable) during production. • Packaging is protected from contamination and stored appropriately. • Staff are complying with and following documented procedures. • Temperature controls (if applicable) are followed in production and storage. • Receival and dispatch areas, equipment, storage devices and vehicles are fit for purpose and sanitary.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

10. Sampling/ Testing			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
10.1 All products produced at the establishment must meet the **microbiological limits f**or food specified by the Food Standards Code and in accordance with the company's Approved Arrangement. The establishment must have procedures in place for finished product pathogen testing that includes: • Identifying pathogens of concern that requires to be tested for each type of product type (eg yoghurt, cheddar cheese). • Defined microbiological limits of the pathogens of concern to be tested. • Every product line must be sampled at a minimum of 5 sub samples per fortnight. Each sub sample must be collected from the same batch. • Describes the collection of samples including that it is done at end of process (after packing). • Where composite testing is requested, identify when this is appropriate (ie for qualitative testing only). • Identify corrective action controls should the limits be exceeded. • Identify any specific importing country requirements that are different to the standard testing requirements. • Identify the Australian Standard test method used. • Identify when product is tested in a NATA accredited laboratory.	C5 P2 S5-26		An export registered manufacturing establishment is required to test finished product for pathogens of concern every fortnight for each product line. Composite testing can only be used for qualitative testing – ie the presence or absence of an microorganism. Examples may include for Listeria monocytogenes. Notifications of failed finished product pathogen testing must occur to your State food regulator and also the Department (Commonwealth) as soon as possible upon receival of a failed result. Corrective action controls must include a documented pathogen clearance program.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

11. Training			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
11.1 The establishment must have a documented program in place for **training** that includes procedures and records. The training program to include: • Induction training, prior to commencement of work in the food handling environment. • Contents of the induction training such as personal health and hygiene, GMP controls and notifications of illness. • Competency of assessment of training program for staff. • Training for relevant roles. • Corrective actions.	C5 P2 S5-37		At audit, staff may be interviewed to verify training has been effective. CCP and GMP training records will reviewed at the audit. Note – the training program must cover off training for all the elements that make up the Approved Arrangement. This could be documented in a training matrix/ register or similar document.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

12. Identification/ Traceability and Recall			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
12.1 Documented systems in place at the establishment must be such that production records are kept, enabling **trace back** to the lot of food and ingredients including: • A description of the food. • Quantity in the lot. • Unique lot identity. • Date of production.	C5 P1 & P2 S5-5 S5-32 S5-5-33 S5-34		At audit, production records will be checked for completeness and where farm milk is received at the establishment, product must be able to be traced back to the tanker run/s used to produce the batch. Where re-work product is blended into a batch of product, it must be traceable to its original batch.

• Full details of all inputs (ingredients). • Trace back to the supplier of ingredients. • Explanation of codes and ciphers used.			Ingredients must be traceable in both non reworked and reworked product.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
12.2 The company must have a documented **recall** procedure in place that includes: • Responsibilities have been allocated for various tasks. • Alternative delegations have been assigned. • Details of the recall process to comply with the requirements of the FSANZ recall guidelines. • Notifications to key government agencies, including the State Regulatory Authority and the Department (Commonwealth). • Recall protocols is tested at least annually and that records are available to support activity. • Linked to corrective action, internal audit and management review.	C5 P1 S5-5		It is expected that the establishment includes notification to the Department if a recall occurs, even if the product is for domestic use only.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

13. Approved Supplier Program; Ingredients and Packaging			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
13.1 The company must have a documented **approved supplier** program in place that includes: • The criteria for approval and the ongoing checks conducted to ensure companies meet supply conditions. • For dairy specific ingredients there must be systems in place that ensure that the goods are only sourced from an export registered dairy establishment. This includes storage establishments. • Approved supplies must be able to demonstrate that they manufacture goods in accordance with the Food Standards Code.	C5 P2 D4 S5-13		At audit, a complete list of all companies approved to supply product/ packaging, chemicals and other inputs is identified as part of the approved supplier program will be sighted. The auditor may request to sight evidence of a selection of inputs that are supports their approval. Evidence sighted might include supplier audit records, accreditation certificates that support use or manufacturer letters that support use. Approved suppliers must meet needs for fit for purpose including where required, that the inputs are "food safe", that is that they can be used in a food environment.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
13.2 Are there documented systems in place to control the supply of **raw milk/ cream** (including temperature and for the EU, TPC, BMCC (somatic cells) and mandatory notification of notification of antibiotics detections). The documented program must include: • The raw milk/ cream is supplied from an approved farm/ supplier. • Notification of on farm non-compliance is included in the company's corrective action program, ie that they are being monitored and closed out. • If applicable, total plate count and somatic cells should be appropriately managed as per EU requirements. • Temperature controls are defined and where hot milk is received, corrective action to what happens next needs to be	C5 P2 D4 S5-13		It is expected that where hot milk is received into the premises (above 5 degrees) that procedures cover validation requirements if wishing to still accept the milk in which includes time and temperature parameters. Information on hot milk validation controls can be found on the Department's website.

detailed. Where the establishment seeks to accept hot milk, a validated process to manage the temperature variation must be clear (for example, using the milk cooling curve/ envelopes). • Controls on antibiotics including notification of failed detections is described.			
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element. Please do not include attachments. It is not acceptable to respond with just "Yes" or "No" responses.			
13.3 If **imported ingredients** are used in the manufacture of milk and milk products, this must be covered in procedures?	Associated to C5 P2 D5 S5-13		If imported ingredients are used, labelling must meet the requirements of the *Trade Practices Act 1974* which contains prohibitions on engaging in conduct that is misleading or deceptive or is likely to mislead or deceive (section 52) and prohibitions on making false or misleading representations, including about the country or origin of milk and milk products (section 53 and section 75AZC). Imported ingredients are included as part of your approved supplier program and evidence to demonstrate that the ingredients are fit for purpose and "food safe", that is that they can be used in a food environment must still be demonstrated. This may include microbiological test reports, overseas manufacturer declarations, import clearance documents from the Department, ect.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

14. Receiving and Dispatching Milk and Milk Products			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
14.1 Are there documented procedures in place for the **receival** of dairy ingredients (including raw milk/ cream where applicable) that includes: • Milk ingredients made in or are product of Australia comes from an export registered establishment (excludes raw milk/ cream coming from farm). • Transfer declarations received for these Australian milk ingredients (excluding raw milk/ cream coming from farm). • Detail what are the minimum details required on a received transfer document. • Detail what are the relevant information for imported milk ingredients such as C of A's, quarantine import clearance, ect. • For ingredients that require temperature controls, checks are in place to verify that temperatures at receival have been maintained. • The cleanliness of the transportation vehicle is checked. • Antibiotic checks are defined and described in detail. • Corrective actions identified including for when goods are delivered outside set requirements (eg temperature limits, lack of paperwork such as no transfer declarations accompanying deliveries, unhygienic transportation vehicle, failed antibiotic testing, outside of approved supplier program). • Receival records defined. • Where milk and milk products are received and not for use in milk and milk products for export, what is in place to ensure they are suitably identified.	C5 P2 D4		It is expected for broad spectrum antibiotic tests on raw milk is undertaken at receival. The collection of samples for each tanker (including multiple compartments) is taken at receivals and not sampled from silos at establishment. The auditor will review a selection of receival records of milk ingredients at audit.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

14.2 Are there documented procedures in place for the **storage** of dairy ingredients, work-in-process (if applicable), product for rework (if applicable) and finished product to ensure product is identified and stored correctly including where required, temperature controls?	C5 P2 D4		The auditor may check temperature monitoring storage records at the onsite audit.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
14.3 Are there documented procedures in place for the **dispatching** of milk and milk products from the establishment including: • Transfer declarations are made for export eligible products. • The cleanliness of the transportation vehicle is checked. • Dispatch checks and relevant records made.	C5 P2 D4		The auditor may review a selection of dispatch records of milk products at audit.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

15. Transfer and Manufacturer Declarations of Compliance			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
15.1 Does the company have a documented program in place for each consignment of milk and milk products dispatched from the establishment to ensure **transfers** are issued (where applicable)? Procedures will: • Identify when a transfer document is required. • Identify the format that the transfer document will take and what is the minimum information that in must be contained. • Who has been authorised by the company to sign these documents (names of individual people).	C5 P2 D8		It is expected that nominated staff have received training and or information about the responsibilities associated with signing these documents.

• A description on what basis the nominated staff can sign these documents. • Identifies that export product can only be sent to an Department export registered dairy establishment. • Identifies how the company knows the receiving establishment is a export registered dairy establishment.			
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
15.2 Does the company have a documented program in place for issuing **manufacturer declarations of compliances**? Procedures will: • Identify when a declaration of compliance is required. • Identify the format that the declaration of compliance will take and what is the minimum information that must be contained. • Evidence to support the issuing of a declaration compliance must be in place. • Must be signed by nominated staff (names of individual people). • How relevant staff verify compliance with specific importing country requirements such as somatic cell counts in farm milk for EU destined product. • The importing country requirements identified in the Approved Arrangement are met and complied with. • That the information on the declaration of compliance is true and complete. • Identify the circumstances when a declaration of compliance cannot be issued.	C5 P2 D8		It is expected that nominated staff have received training and or information about the responsibilities associated with signing these documents.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

16. Importing Country Requirements			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
16.1 Are there documented procedures and training in place for ensuring compliance with identified **importing country requirements** being met? The documented system will identify: • How importing country requirements are identified. • How does the company check that importing country requirements are met. • What records are kept to ensure that these requirements have been met. • A list of countries identified as export markets (eg EU, South Korea, Algeria).	C5 P2 D2 S5-7		The auditor may interview relevant staff on knowing how to identify importing country requirements at the audit. Note – certain countries such as the EU will require specific additional requirements to be added to the Approved Arrangement for assessment.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

17. Loading of Sea and Air Freight Containers			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
17.1 Does the company **load directly into sea/ air freight containers**? If so, a documented procedure must be in place to ensure the containers are: • Fit for purpose. • Clean and free of extraneous matter and residues. • Free of objectionable odours, taints and other toxic substances. • Free of dirt, rust, flaky paint, algae growth and moisture. • Free of insects and other pests.	C5 P2 D4 S5-21 S5-22 S5-23 S5-24		If you are loading into transport vehicle only, procedures for those controls to be defined in dispatch controls. If loading into sea and air freight containers then these checks must be included into your procedures.

• No protruding fixtures which could penetrate and damage packaging containing milk and milk products. • Floor is sound, vents are checked and where temperature control is required it is checked and working. • Records in place for these checks.			
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

18. Departmental (Commonwealth) Applied Seals			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
18.1 If a **sealing system** is required, a documented program must be in place and include: • How the company orders the seals from the Department. • Seals must be stored in a secure location with limited access to those staff responsible for the reconciling of them. • A reconciliation process in place for identifying number of seals received and use of. • Staff allocated responsibilities for seal management are aware of the procedures and work instructions. • Corrective actions and verification controls in place. • Records must be made.	C5 P2 D2 S5-7 C8 P2		A self-sealing program with Departmental seals is only required for certain overseas destinations as it is an importing country requirement. Currently milk/ milk products to USA and liquid milk to Fiji requires this. Reconciliation controls must include: • A seals register that details date of receipt of the seals received by the establishment. Receipt dates can identify the sequential number range of received (from example, numbers 501 to 600). • Identified when a seal has been used, on what date, what container it has been applied for and for what purpose. Every individual seal once used must be detailed. • If a seal has been damaged, this must still be reconciled.

			• Seals are stored in a secure and lockable cabinet or similar furniture and accessed by staff who are responsible for their control.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

19. Pasteurisation and Other Heat Treatment Processes			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
19.1 Does the company use **batch pasteurisation** as a means of heat treatment? If so, the company will need to include: • How the heat treatment system has been validated. • The system is supported by an independent evaluation of the pasteuriser and its effectiveness. • A continuous reading of temperature and time. • If there is heated head space and how this is controlled. • If there is an ongoing phosphatase testing regime in place, how is this managed and described in procedures. • Defining daily verification checks in place and that these are described in procedures. • Procedures includes training, corrective actions and notification of failed results.	C5 P2 S5-17 S5-19		Validation evidence to demonstrate that each batch pasteuriser onsite must be available for the auditor to assess. Validation evidence includes: • An executive summary describing the details of the heat treatment process and each type of pasteuriser that is used. • The summary must identify where the temperature probes are located, type of agitation used and the that the connections of pipes between raw and treated milk is separated so cross contamination cannot occur. • The summary must describe the types of milk and milk products that will be batch pasteurised. • Defined critical limits established based on the effective kill of the target organisms of concern. • Supporting data to demonstrate that effective pasteurisation for temperature and time to be captured and must be achieved.

			• Consideration of placement of temperature monitoring probes (eg slowest heating spot; headspace) is important to ensure accurate temperature readings. The auditor will review validations of batch pasteurisation if used as part of the onsite audit. The auditor will also sight batch pasteurisers during the site walkthrough.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
19.2 Does the company use **HTST pasteurisation** as a means of heat treatment (heat treated to not less than 72 degrees for 15 seconds)? If so, the company will need to include: • How the heat treatment system has been validated. • That temperature monitoring devices such as probes and chart records are regularly calibrated (at least annually). • That integrity checks of the plate packs are conducted at least annually. • That integrity plate checks are conducted on all cooling units that use glycol or other chemicals as their cooling medium (eg at milk receival). • That the diversion valve operation is tested recorded and signed daily. • That the holding tube is in a continuous upward slop in the direction of flow. • That the diversion valve is in the correct position (based on response time). • That all the thermometers are in the corrective position. • That the sanitation of the pasteuriser is effective (how is this demonstrated).	C5 P2 D4 S5-17 S5-19		At audit, the company must supply evidence that the pasteuriser meets requirements including providing certificates of calibration or commissioning. Examples of records includes temperature monitoring probes/ sensors such as from entry and exit of holding tube, plate integrity tests, reaction/ response times, ect. The auditor will also sight the HTST pasteurisers during the site walkthrough.

• That the holding tube time is calibrated every 5 years or after the system is changed. • That a phosphatase test can be conducted on every batch of pasteurised milk. If not, what is the frequency of phosphatase testing. • The the company has a documented procedure for conducting these tests. This procedure includes training, corrective actions and notification for failed results. • Suitably qualified persons for all key devices (eg pasteurisers).			
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
19.3 Does the company use **an alternative heat treatment such as ESL/ UHT processes** as a means of heat treatment? If so, the company will need to include: • Detail how the heat treatment has been validated. • That temperature monitoring devices such as probes and chart records are regularly calibrated (at least annually). • Daily monitoring checks defined and controlled. • Key instruments are calibrated and verified.	C5 P2 D4 S5-17 S5-18 S5-19		Validation evidence to demonstrate that the alternative heat treatment process is effective. Evidence at the onsite must be available for the auditor to assess. Validation evidence will vary depending on the process but may involve: Validation evidence includes: • An executive summary describing the details of the heat treatment process and each type of equipment used. • The summary must identify key measuring devices. • The summary must describe the types of milk and milk products that will be heat treated with the alternative process. • Defined critical limits established based on the effective kill of the target organisms of concern. • Supporting data to demonstrate that effective heat treatment for temperature and time to be captured and must be achieved or commissioning/ manufacturing specifications are met such as temperature probes calibrated, heat exchanges in place and working, ect.

Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.

20. Trade Description			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
20.1 Is there a documented system in place for ensuring export labels and other **trade description** that appears on the packaging are accurate, current and in accordance with minimum export requirements? The program must describe the minimum contents that make up an export trade description that must include: • A description of the milk and milk products. • Where milk and milk products contain more than one ingredient, a list of ingredients in accordance with the requirements specified in Standard 1.2.4 of the Food Standards Code. • The net contents (the quantity of milk and milk products in a container). • The country of origin. • The registration number of the establishment at which the milk and milk products are last prepared (other than handled, loaded or stored). • The name and address of the exporter, occupier or consignee. • The identify of the lot for the milk and milk products. • The directions for the use or storage if the milk and milk products are of a nature as to warrant such directions for reasons of food safety.	C5 P2 D5		Compositional claims must be supported and verified by the company. Shelf life validation to support use by and best before dates must be in place. The auditor may request evidence to support compositional claims or shelf life validation at the onsite audit. The auditor may sight examples of trade description at the onsite audit.

The program must include: • Criteria to meet if foreign languages are used. • Specific importing country requirements (eg use by or best before date format). • Compositional claims must be verified. • Where there is multiple container (packaging) the trade descriptions requirements may vary to the primary container. Must be defined if different and meets export legislation.			
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

21. Maintenance and Calibration			
Element	**Act/ Rules**	**Comply (Y/N)**	**Comments**
21.1 Does the company have a documented **maintenance program** in place and includes: • A preventative maintenance program that identifies a schedule of regular maintenance activities, including a list of equipment with a defined frequency and checks identified? • A reactive (eg break downs) maintenance program that identifies the controls in place to when equipment or structure is affected. Controls include whether production can or cannot continue and why as well as isolation/ tag out process and clearance checks required before equipment can be reintroduced back into production or area can be restarted for production (eg recleaning, reinspection then release)?	C5 P2 D3 S5-9		It is expected that the preventative maintenance program will cover systems that ensure that: • The premises and equipment are maintained in a good state of repair. • Transport vehicles used by the premises are maintained in good repair. • A schedule of regular maintenance activities is identified with frequencies and records made. • Links back to corrective actions, internal audits, ect. At audit, a walkthrough of the premises will verify the state of good repair of structure and equipment. This includes but not exhaustive to ceilings, walls, floors, fixtures (including lights) and equipment.

Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			
21.2 Does the company have a documented **calibration program** in place and includes: • A list covering all equipment requiring ongoing calibration? • Schedule of calibration activities including frequency, responsibility and tolerance limits? • Work instructions or procedures that detail how internal calibrations are performed (eg calibration of a pH meter or calibration of a hand held temperature probe).	C4 P1 S4-3 C5 P2 S5-10		At audit, key measuring instrument calibration records may be checked, especially if they are involved in the monitoring of significant hazards and CCPs.
Provide a brief description of how you meet compliance including referencing any documents/ procedures that you have in place for this element.			

Any additional questions or comments for the Dairy export facilitator: