



Australian Government

Australian Quarantine and Inspection Service

Approved Arrangement

For establishments that manufacture dairy products for export purposes

**A Guideline to Compliance with the
*Export Control (Milk and Milk) Orders 2005***

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1.0 Objectives

This guideline addresses the requirement of registered establishments to comply with Order 38 of the Orders by documenting, implementing and complying with an auditable system of controls and procedures – an “Approved Arrangement”.

2.0 Scope

This guideline has been developed to assist registered establishments and authorized officers in the development, implementation, maintenance and auditing of Approved Arrangements.

3.0 Background

The *Export Control (Milk and Milk Products) Orders 2005* require that occupiers of registered establishments have an Approved Arrangement in place. The Approved Arrangement must document systems that deliver compliance with legislative and importing country requirements.

The guideline provides recommendations and guidance only. Reference to the guideline and documenting appropriate controls as described will assist in the development of an Approved Arrangement that is acceptable to AQIS. The document also refers to mandatory requirements that arise from legislation. It should be noted that options are provided for alternative regulatory arrangements – see 5.6.12.

Establishments manufacturing milk and milk products may choose to use other tools in the development of an Approved Arrangement. However, all aspects affecting the safety and suitability of milk and milk products must be detailed in the Approved Arrangement along with any specific importing country requirements and measures necessary for ensuring that there is a sound basis for issuing export documentation.

4.0 Who needs an ‘Approved Arrangement’?

Occupiers of all establishments registered to produce milk and milk products for export must have an Approved Arrangement in place.

5.0 Components of an Approved Arrangement

5.1 Introduction

- Scope & purpose of the approved arrangement

In documenting an approved arrangement the occupier of the establishment must be able to clearly identify the following:

- Scope of the arrangement – identify products and processes to be addressed by the approved arrangement. This should include the start and end points of processing, eg liquid milk production from receipt of raw milk to despatch of packaged pasteurised milk.
- Purpose of the arrangement – identify why the Approved Arrangement has been developed and implemented. This may include ensuring the safety and suitability of the dairy products as well as ensuring compliance with both export legislation and importing country requirements.

5.2 Management & Establishment details

- Establishment number
- Management & contact details
- Identification of products produced at the establishment

The approved arrangement should identify the premises and products that it seeks to cover. Key contacts should be provided.

5.3 Management Practices (Orders 31-32 and Schedule 2)

- Occupier's commitment
- Management practices, organisational structure
- Communication – with AQIS, State Regulatory Authorities – obligation to notify

Occupier's commitment

Export Control (Milk and Milk Products) Orders 2005 - Schedule 2

Occupier's commitment

- 1.1** The commitment of the occupier to:
- (a) the objectives specified in suborders 3.1 and 3.2; and
 - (b) compliance with the requirements of these Orders and applicable importing country requirements;
- must be documented.

The occupier of an establishment used to prepare milk and milk products for export must make a statement in the Approved Arrangement, which commits the occupier to meeting the requirements of the *Export Control (Milk and Milk Products) Orders 2005* including HACCP plan requirements and importing countries requirements.

Management practices, organisational structure

Export Control (Milk and Milk Products) Orders 2005 - Schedule 2

- 4.1** The management practices, organisational structure, provision of resources and the provision of personnel and their competence (including knowledge, training, skills and experience) must:
- (a) be documented; and
 - (b) be appropriate to ensure each of the following are met:
 - (i) the applicable requirements of these Orders;
 - (ii) the applicable importing country requirements.

The Approved Arrangement must document the:

- Management practices - a mission statement/policy statement

Example:

In developing and **signing a Policy Statement**, the occupier is demonstrating his/her intention to:

- Endorse how the Approved Arrangement is central to the effective operation of the establishment, and
- Give company commitment to comply with legislative requirements.

In this respect it is the same as the **Occupier Commitment**, but a Policy Statement may also include:

- A statement on the organisation's objectives, including performance improvement and commitment to maintaining product integrity and the preparation of safe and suitable products for export.

The Occupier Commitment can be included in the Policy Statement.

- Organisational structure

Example:

The organisation chart should include names and titles of:

- Senior management
- All persons in management and control of operations at the establishment and a brief description of their roles and responsibilities
 - Including Quality Managers

- Communication

The Approved Arrangement must document procedures necessary to ensure communication is adequate to ensure compliance with the requirements of export legislation and importing country requirements with notification of both AQIS and State Regulatory Authorities as required. This includes maintenance of current information (eg in registration details) and communication as part of emergency management (eg animal health disease outbreak or export of noncompliant milk and milk products).

5.4 HACCP Plan (Order 3 Schedule 2)

An approved arrangement must have a HACCP Plan which addresses all milk and milk products identified in the establishments export registration.

The *Export Control (Milk and Milk Products) Orders 2005* require that an Approved Arrangement include a HACCP Plan. Requirements for HACCP are well documented and the legislation particularly references Codex.

- Link to Codex HACCP and guides to its' application - http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y1579E/y1579e03.htm
- Various additional documents are referenced in Section 7.0 Guidelines and References.

In summary, the HACCP Plan must identify:

- Each of the steps in the preparation of the food (a flow chart may be used); and
- The potential hazards that may reasonably be expected to occur; and
- The means of control of each potential hazards; and
- The critical control points (CCP) for each significant hazard; and
- The critical limit that must be met for each critical control point; and
- The procedures used to monitor the significant hazards to ensure compliance with each critical limit including:
 - The frequency at which monitoring will be performed; and
 - The person/persons (including a class of persons) who will carry out these procedures; and
- The corrective action to be taken if a critical limit is exceeded; and
- Verification procedures and the frequency with which these procedures will be performed; and
- The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.

Key Areas of Consideration

When conducting the risk assessment for your HACCP Plan considerations should be given to the following issues:

- Sourcing (Schedule 5, Part 1) including raw milk & on farm requirements, ingredients, including imported ingredients, and raw materials of dairy and non dairy origin
- Chilling, freezing, thawing and tempering (Schedule 5, Part 2)
- Preserving milk and milk products including pasteurisation (Schedule 5, Part 3)
- Packaging (Schedule 5, Part 4)
- Preparation and Transport (Schedule 5, Part 6)
- Fitness for human consumption (Schedule 5, Part 7)

5.5 Verification and Validation

Verification (Schedule 2, Clause 5.1) - The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

- Internal audit and management review (Schedule 2, Clause 7)
- Validation - Obtaining evidence that the elements of the HACCP plan are effective

Verification

The occupier must document how he/she verifies compliance with:

- The requirements of Division III of Part 3 of the *Export Control (Milk and Milk Products) Orders 2005* – Export Standards;
- Identified importing country requirements; and
- The requirement that the results of all verification activities must be recorded (Schedule 2, clause 6).

To ensure compliance with this requirement the occupier of the Registered Establishment needs to document in the Approved Arrangement how procedures, tests or other assessments are conducted to ensure that each of the relevant requirements in the Schedules listed above are met.

AQIS has developed guidelines to assist you in documentation of Schedule 6, 7 and 8. These can be found at www.aqis.gov.au/dairy.

Internal audit and management review

The Approved Arrangement must document procedures for internal audit of your own Approved Arrangement and conduct of management reviews. These activities must assess that:

- The Approved Arrangement reflects current products, processes and control measures;
- The approved arrangement is complied with;
- There is documented evidence of compliance;
- Changes to technology, processes, markets supplied, importing country requirements or legislation have been identified and addressed in the Approved Arrangement; and
- Action is taken to address areas of non-conformance identified through these reviews.

Internal audit and management review must be:

- Conducted at least once every twelve months; and
- Records of the reviews and audits conducted

Exception: Establishments employing less than 3 people are considered to have conducted an internal audit of the Approved Arrangement if a management review is conducted. (Schedule 2, clause 7.3).

Example:

Internal Audit

A method of internal auditing may consist of rolling audits. Rolling audits may be scheduled to look at different parts of the Approved Arrangement over time so that the entire arrangement is audited once or twice per year. The audits should be conducted in a systematic way, with an audit checklist, identification of non-conformances, follow up and close out of non-conformances. A record of the audit and associated corrective actions should be kept.

Example:

Management Review

A management review could be a monthly meeting of key staff where aspects of operations, reviews of internal and external audits are considered and future planning of operations occurs. The meeting should:

- Be undertaken by nominated responsible personnel, eg senior management and QA staff
- Review internal and external audit outcomes
- Review the outcomes (if relevant) of overseas reviews, customer complaints, detained consignments, monitoring and verification activities to identify breakdowns in systems which need improvement,
- Consider corrective actions that may need to be implemented eg. Maintenance program and consider any incidents that may have occurred since the last meeting.

The outcome of the meeting is to ensure the ongoing compliance of the Approved Arrangement to meet legislative requirements.

Sampling and analysis (Schedule 2 Clause 8)

Product testing is conducted to verify that the Approved Arrangement is effective in producing milk and milk products that comply with required export standards and /or importing country requirements. The Approved Arrangement must document the sampling and testing regime adopted by the establishment to comply with Schedule 6 Product Standards of the Milk Orders.

The Australia New Zealand Dairy Authorities' Committee (ANZDAC) has set some minimum testing requirements for dairy products. Details can be found in the guideline "ANZDAC Minimum Sampling Requirements for the Australian Dairy Industry". This guideline provides nationally agreed standards for minimum testing required for each category of dairy product, samples sizes, frequency of testing; and limits not to be exceeded. However, HACCP analysis must consider whether the minimum provides a representative and statistically valid verification of the dairy product to be tested. The guideline is available at www.aqis.gov.au/dairy

The minimum testing specified in the ANZDAC guideline is mandatory and will provide the occupier with verification of the HACCP plan. The Approved Arrangement must document the testing regime, identifying both minimum testing and importing country requirements where applicable. These test results underpin certification provided by AQIS to several importing countries where there are known standards.

The methods used for sampling and testing must be in accordance with the requirements of the *Export Control (Milk and Milk Products) Orders 2005*. If this is not specified in the *Export Control (Milk and Milk Products) Orders 2005* refer to a method:

- specified in the Food Standards Code, or
- specified in a relevant standard published by Standards Australia, or
- another method which has been scientifically validated in accordance with the AS 4659.

The Approved Arrangement must also identify systems that verify the appropriateness, veracity and effectiveness of the laboratory testing and testing procedures.

The Approved Arrangement must also identify systems in place to monitor or minimise other contaminants that may adversely affect the prepared food or the presence of any additives. This may include the nationally co-ordinated AMRA survey and incorporate procedures for detection of foreign matter including metal and glass.

Validation

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan. Validation provides evidence and information to confirm that measures developed to control critical processes will be effective. This may include:

- Scientific evaluation of processes and standards;
- Reference to legislated requirements;
- Reference to recognised scientific standards and papers; and
- Historical data.

The Orders also require validation of equipment including refrigeration chambers and pasteurisation & other treatment equipment (Schedule 4, Clause 12; and clauses 4 to 10 and 16 and 17 of Schedule 5.)

Example:

The Food Standards Code specifies temperatures for storage of perishable foods. Reference to this Code can be used to validate the setting to a critical limit for food storage temperatures.

5.6 Summary of Support Programs (Orders 40, 41, 42 and Schedule 3, and 5)

5.6.1 Sourcing (Schedule 5, Part 1)

- Raw milk
- Dairy products as ingredients, including imported ingredients
- Non-dairy ingredients, including imported ingredients

5.6.2 Hygiene

- Cleaning and sanitising of premises, equipment and transport vehicles (Schedule 4, Clause 2-4)
- Pest control program (Schedule 4, Clause 7)

5.6.3 Good Manufacturing Practice

- Use and storage of hazardous substances (Schedule 4, Clauses 8, 9)
- General controls for storage of food, including protection from contamination, storage, handling and transportation (Schedule 4, Clause 10)

5.6.4 Equipment & Premises

- Maintenance of establishments and equipment (Schedule 4, Subclause 3.4) to ensure compliance with the applicable requirements of Schedule 3 (Structural requirements) and Order 40
- Calibration of measuring equipment (Schedule 4, Clause 11)

5.6.5 Food Handling

- Control for ingredients including fitness for purpose, labelling, storage and handling (Schedule 4, Clause 13)
- Water usage and testing including chilled water (Schedule 4, Clause 14, 15, 16 & 17)
- Use of compressed air and other gases (Schedule 4, Clause 18)
- By-products, further processed & reworked product (Schedule 2 Part 1, Schedule 5 Part 1, Clause 7, Parts 3 and 4)
- Presence of potentially harmful substances (Schedule 5 clause 1.1)

5.6.6 Personal Practices

- Personal hygiene and health requirements (Schedule 4, Clause 19-24)

5.6.7 Maintenance of currency of Registration details (Orders 29 & 30 and Schedule 1 and Part 4 of Export Control (Prescribed Goods General) Orders [PGGOs])

5.6.8 Trade description (Order 44 and Schedule 7)

- Contents of the trade description (Schedule 7 Part 2)
- Requirement to provide translations (Order 76)
- Requirements to comply with the *Trade Practices Act* (Schedule 7 Part 2)

5.6.9 Identification, tracing systems, integrity and transfer (Order 45 and Schedule 8)

- Identification and tracing systems (Schedule 8 Part 1) including Production records (Schedule 8 clause 4)
- Sourcing raw milk, milk products for further manufacture and other ingredients, including imported ingredients (Schedule 8 clause 3.1)
- Transfer of milk and milk products (Schedule 8 Part 3)

- Declaration of Compliance (Schedule 9 Division II)

5.6.10 Control of non-conforming product (Schedule 2 Part 1)

- Hold and/or release procedures
- Product recall
- Notification to regulatory authorities
- Preventative action (Schedule 2, Clause 6)

5.6.11 Training and competency

- Resources and competence (Schedule 2, Clause 4.1), including knowledge, training, skills and experience.
- Particular consideration should be given to competence of staff responsible for control of Critical Control Points and/or critical operations.

5.6.12 Miscellaneous

- Control and security of official marks and marking devices (Order 64)
- Alternative regulatory arrangements (Order 78)

5.6.13 Record keeping and documentation control

- Retention for 3 years
- Record keeping and document control (Schedule 2, Clause 10)

The support programs documented within the Approved Arrangement shall identify the procedures necessary to demonstrate:

- How compliance with the elements of the Approved Arrangement is to be achieved;
- Who is responsible;
- Where it is substantiated in records;
- How it is checked (including by whom, signature and date); and

- Frequency of procedures and checks.

5.6.1 Sourcing

Sourcing of milk, milk products and ingredients of milk and milk products to be exported (Schedule 5, Part 1)

Milk and milk products or their ingredients for export must not be sourced from areas where there are reasonable grounds to believe that potentially harmful pathogens, or harmful substances like pesticides, fungicides, heavy metals, natural toxicants or other contaminants occur or could result in them being present in the food in an unacceptable level. Imported ingredients must be considered and appropriately managed with due consideration given to export certification implications. In assessing compliance with this requirement consideration should be given to the source of stockfeed or water used for stock or for cleaning etc in establishments.

If you are sourcing milk and milk products for use in preparing milk and milk products then it must come from:

- Another AQIS Registered Establishment
- From an unregistered establishment with an approval given by the Secretary in accordance with clause 7 of Schedule 1; or
- A farm with an appropriate system in place (see farm supply below).

The Approved Arrangement must include systems of controls to ensure that milk is obtained from sources that ensure that the milk and milk products to be prepared will be safe/suitable.

Farm supply – Dairy farms supplying establishments must have systems in place to ensure that following controls are in place (as required by the *Export Control (Milk and Milk Product) Orders 2005* Schedule 5 Clause 2.3):

- (a) disease management controls in place to ensure only healthy animals are used for milking; and
- (b) effective measures in place to ensure:
 - (i) animals for milking are not given feed or treated with a substance that could adversely affect the fitness for human consumption of milk and milk products; and
 - (ii) the collection, storing and chilling of milk is done under conditions that ensure the fitness for human consumption of milk and milk products is not adversely affected; and
 - (iii) as soon as practicable after milking, the milk is placed under temperature controls that minimise the growth of pathogens that could adversely affect the fitness for human consumption of milk and milk products.

Compliance with sourcing requirements can be achieved through sourcing milk from suppliers with appropriate on-farm food safety programs and non-dairy ingredients from establishments with appropriate HACCP-based systems.

The Approved Arrangement must include systems to ensure that delivery of milk from the farm ensures traceability and temperature controls are in place.

Non-dairy ingredients and food contact materials - The Approved Arrangement must provide evidence that all ingredients and food contact materials such as packaging are fit for the intended use and will not adversely affect the fitness for human consumption.

5.6.2 Hygiene

- Cleaning and sanitising of premises, equipment and transport vehicles (Schedule 4, Clause 2-4)
- Pest control program (Schedule 4, Clause 7)

- General Hygiene and cleaning requirements (Schedule 4, Part 1)

Example:

A documented procedure is provided identifying controls relating to cleaning and sanitation, including

- Equipment to be cleaned, identifying frequency, chemical used, monitoring.
- Cleaning-in-place (CIP) systems require detailed standards on chemical concentration, wash temperatures and contact time.
- Sanitation of equipment
- Environmental cleaning (walls, floors, establishment surrounds.)

Documenting a procedure that sets out a program of regular surveillance of the Establishment and the equipment would verify compliance with this clause of Schedule 2.

- Pest control

The approved arrangement must include an adequate pest control program. This program must endeavour to ensure that pests and their control do not present a food safety risk at the registered establishment.

Example:

Information which may be included in a pest control program:

- Information relating to commercial pest controllers if appropriate, including frequency of treatment, reporting etc. This information may be included in the contract with the agent;
- bait station map;
- identification of chemicals used and their suitability for use in a food handling establishment;
- identification of all potential pests that may enter the establishment;
- identification of all potential pests controlled by the program, eg rodents, spiders
- pest sighting and recording procedures
- consideration of seasonal pest issues
- corrective action
- verification procedures (company staff verification of contractor effectiveness)

5.6.3 Good Manufacturing Practice

- Use and storage of hazardous substances (Schedule 4, Clauses 8, 9)
- General controls for storage of food, including protection from contamination, storage, handling and transportation (Schedule 4, Clause 10)

Use and storage of hazardous substances (Schedule 4, Clauses 8 and 9)

The Approved Arrangement must include systems in place that ensure that hazardous substances are appropriately controlled and secured to ensure that milk and milk products cannot be contaminated.

Storage, handling and loading (Schedule 5, Part 5)

The Approved Arrangement must include systems of control for the storage, handling and loading of milk and milk products to protect the milk and milk products from contamination and to ensure that the fitness for human consumption is maintained.

Example:

Procedures should ensure that cartons of frozen packed product are not stored directly on the floor of a cold store or where condensation can come in direct contact with the carton or its contents. They should ensure that dried packed product is not left open to the elements, where humidity could cause mould or the product can absorb water vapour and encourage pathogen growth.

5.6.4 Equipment & Premises

- Maintenance of establishments and equipment (Schedule 4, Subclause 3.4) to ensure that milk and milk products for export as food are prepared in an establishment where there is compliance with the applicable requirements of Schedule 3 (Structural requirements) Order 40
- Calibration of equipment used for monitoring of critical processes (Schedule 4, Clause 11)
- Validation of equipment including refrigeration chambers and pasteurisation & other treatment equipment (Schedule 4, Clause 12; and clauses 4 to 10 and 16 and 17 of Schedule 5)

The Approved Arrangement must provide adequate programs for maintenance of the establishment and equipment; calibration of equipment; and validation of equipment including refrigeration chambers and pasteurisation or other treatment equipment. Where available it is recommended that Australian Standards be considered and followed.

5.6.5 Food Handling

- Control for ingredients including fitness for purpose, labelling, storage and handling (Schedule 4, Clause 13)
- Water usage and testing, including chilled water (Schedule 4, Clause 14, 15, 16 & 17)
- Use of compressed air and other gases (Schedule 4, Clause 18)
- By-products & reworked product
- Presence of potentially harmful substances (Schedule 5 clause 1.1)

Control of ingredients including fitness for purpose, labelling, storage and handling (Schedule 4, Clause 13)

The Approved Arrangement must detail procedures for receipt of ingredients, including Supplier Programs providing traceability and fitness for human consumption, use of ingredients, labelling, storage and handling of the ingredients to ensure that when added to milk and milk products that the final product is fit for human consumption in accordance with the requirements of Schedule 6 of the *Export Control (Milk and Milk Products) Orders 2005*.

Water usage and testing including chilled water, recycled water and water reclaimed from milk and milk products (Schedule 4, Clause 14, 15, 16 & 17)

The Approved Arrangement must detail the requirements for sampling, testing and obtaining test results for water.

- Microbiological test results must be obtained for water sourced directly from the registered establishment.
- Chemical test results, against the Australian Drinking Water Guidelines, can be obtained from the water supplier annually.

The Approved Arrangement must also detail procedures that ensure that chilled water or recycled water or water reclaimed from milk and milk products does not contaminate milk and milk products.

Water for processing has to be potable or you have to nominate where you use a particular form of water. If it comes into contact with the milk and milk products or food surfaces you will have to verify that it will not contaminate milk and milk products for export.

For any type of water used, you will either have to:

- (a) Verify that the water is potable and meets the microbial limits which have been set;
- (b) Verify that it does not come into contact with milk and milk products or food surfaces; or
- (c) Verify that it does not contaminate the milk and milk products.

For (a) above you need to test water and for (c) you will need to test the product.

An Approved Arrangement will not be approved by AQIS unless these controls have been documented.

AQIS requires at least monthly water testing as required by the microbiological standards in Subclause 15.1 of Schedule 4 of the *Export Control (Milk and Milk Products) Orders 2005* conducted at a NATA accredited laboratory registered for the tests required in Subclause 15.1.

There are other events which should automatically trigger testing of water

- (a) When work has been done on sewage or water piping in your establishment
- (b) When you commission new refrigerators or ice makers or after breakdowns and repairs
- (c) When there has been flooding or heavy rains which may cause back siphonage of reticulation systems or sewage systems

- (d) When there is obvious discolouration of the water, if it contains particles of matter or has an offensive odour or oily film.

Example:

Procedures should include the following features:

- Rotation of sampling points through all water sources in the registered establishment
- How the sample should be taken
- Who should take the sample
- Training and approval of sample takers
- The checks made to ensure that sample and results are received by the end of each calendar month
- Map of the water supply and supply points at the registered establishment
- Details of the test methods utilised, as per the *Export Control (Milk and Milk Products) Orders 2005*
- Notification to AQIS and State Regulatory Authorities in the event of failure to comply with the *Export Control (Milk and Milk Products) Orders 2005*
- System for holding product produced when the water does not comply with the *Export Control (Milk and Milk Products) Orders 2005*

Use of compressed air and other gases (Schedule 4, Clause 18)

The Approved Arrangement must provide procedures to ensure that, where used, compressed air and other gases do not contaminate milk and milk products.

By-products & reworked product

By-products and reworked product must be incorporated into the Approved Arrangement with details indicating how the products are to be utilised and how these products will be handled and/or processed to ensure that milk and milk products are not contaminated.

Presence of potentially harmful substances (Schedule 5 clause 1.1)

The Approved Arrangement must document how the occupier will ensure that milk and milk products are not sourced from areas where there is reason to believe the product may be contaminated with pathogens or other potentially harmful substances.

5.6.6 Personal Practices

- Personal hygienic and health requirements (Schedule 4, Clause 19-24)

The Approved Arrangement must detail adequate staff training practices and procedures to ensure that hygienic practices required by the *Export Control (Milk and Milk Products) Orders 2005* are complied with. The procedures must also indicate how the occupier will ensure that no persons with an infectious disease or suspected of carrying an infectious disease will come into contact with milk and milk products either directly or indirectly.

5.6.7 Maintenance of currency of Registration details (Orders 29 & 30 and Schedule 1 *Export Control (Milk and Milk Products) Orders 2005* and Part 4 of *Export Control (Prescribed Goods General) Orders [PGGOs] 2005*)

- Milk and milk products must be prepared in a registered establishment or an approved unregistered establishment (Orders 29 and 30)
- Plans and specifications (Part 1 Schedule 1)
- Registration requirements (Order 4.04 PGGOs)
- Certificate to be displayed (Order 4.10 PGGOs)
- Changes of which Secretary must be notified (Division 4.4 PGGOs)
- Alterations or additions (Division 4.5 PGGOs)
- Variation of export operations (Division 4.6 PGGOs)

The Approved Arrangement must detail how the occupier will comply with the requirements of Schedule 1 which provides the mechanism for the requirements of Part 3 of the *Export Control (Milk and Milk Products) Orders 2005* and details the requirements for plans and specifications, of the premises. The plans must be available when applying to be registered as an export dairy establishment and provided as required by auditors. The plans must include water supply and equipment. New plans must be submitted when alterations and additions are proposed.

The currency of registration details should be checked for accuracy during the management review of the approved arrangement.

Export Control (Milk and Milk Products) Orders 2005 – Schedule 1

Plans for establishments

- 2.1** The plans must include:
- (a) a locality map showing the site; and
 - (b) a site plan showing:
 - (i) the layout of the entire premises; and
 - (ii) access roads and roads at the establishment; and
 - (iii) the water supply; and
 - (iv) stormwater and waste water drainage; and
 - (v) on site waste disposal (if any); and
 - (vi) the amenities; and
 - (vii) all features of the site and its location that are relevant to whether the premises would comply with the applicable requirements of these Orders; and
 - (viii) adjoining sites including location of adjacent establishments; and
 - (ix) the north compass point; and
 - (x) the scale used in the plan; and
 - (c) a floor plan of all milk and milk product handling areas (including laboratories) showing all permanent fixtures and the layout of equipment (other than implements and utensils); and
 - (d) a description of all equipment (other than implements and utensils) for use in the preparation of milk and milk products at the premises.

Note For the meaning of *equipment* and *food handling area* see order 7.

Details to be shown in specifications

- 3.1** The specifications must show details of:
- (a) construction materials of the premises including fixtures; and
 - (b) construction materials of the equipment (other than implements and utensils) used in food handling areas; and
 - (c) surface finishes; and
 - (d) surfaces in contact with milk, milk products or ingredients; and
 - (e) essential services.

5.6.8 Trade description (Order 44 and Schedule 7)

- Contents of the trade description (Schedule 7 Part 2)
- Requirement to provide translations (Order 76)
- Requirements to comply with the *Trade Practices Act* (Schedule 7 Part 2)

Schedule 7 describes the requirements relating to Trade Descriptions. The Approved Arrangement must describe the procedures put in place to ensure that accurate trade descriptions are applied to milk and milk products for export (Clause 1). Information is also provided relating to trade descriptions for bright cans or unwrapped, milk and milk products bulk loaded into a container (Clause 2) and milk and milk products identified as not for retail sale (Clause 3).

AQIS has developed an information sheet titled “Trade Description” - A Guideline to Compliance with the *Export Control (Milk and Milk Products) Orders 2005*” to help you document procedures in your Approved Arrangement. The guideline is available at www.aqis.gov.au/dairy

5.6.9 Identification, tracing systems, integrity and transfer (Order 52 and Schedule 8)

- Identification and tracing systems (Schedule 8 Part 1) including Production records (Schedule 8 clause 4)
- Sourcing raw milk, milk products for further manufacture and other ingredients, including imported ingredients (Schedule 8 clause 3.1)
- Transfer of milk and milk products (Schedule 8 Part 3)
- Declaration of Compliance (Schedule 9 Division II)

Establishments preparing milk and milk products must have effective measures (including records and documentation) in place for the identifying, tracing and, if necessary, recalling of milk and milk products. (Schedule 8, clause 1.1)

Where milk and milk products are transferred as part of an inter-company transfer, alternative systems for product traceability may be implemented provided the Approved Arrangement documents the controls in place (Schedule 8, clause 10.1). Schedule 8, clause 7 provides details of information must be provided on despatch.

The concept of effective traceability relies on everyone in the through-chain taking responsibility for how they handle the food. All food received into an Establishment must comply with the Orders and must be accompanied by an appropriate transfer document, which contains a declaration stating that the food complies with the Orders and any importing country requirement. See information sheet on “Approved Transfer Systems” Documents.

AQIS has developed several guidelines including “Traceability - A Guideline to Compliance with the *Export Control (Milk and Milk Products) Orders 2005*” and “Approved Transfer Systems”. These documents will assist you in documenting procedures in your Approved Arrangement. The guidelines are available at www.aqis.gov.au/dairy.

Guidelines are also provided in relation to requirements for Declarations of Compliance as required by Division II of Schedule 9 of the *Export Control (Milk and Milk Products) Orders 2005*.

5.6.10 Control of nonconforming product

- Hold and/or release procedures
- Product recall
- Notification to regulatory authorities
- Preventative action (Schedule 2, Clause 6)

The Approved Arrangement must provide procedures that control nonconforming product. These must include appropriate hold and/or release procedures, product recall including notification to AQIS and State Regulatory Authorities, and appropriate preventative action to ensure that all product exported does meet the requirements of the *Export Control (Milk and Milk Products) Orders 2005*. Guidelines in relation to requirements for product recall are provided by FSANZ.

Notifiable diseases

The occupier of the Registered Establishment should familiarise themselves with **Schedule 2 Clause 10** which relates to notifying an authorised officer if animals from which food is being prepared is affected by or suspected of being affected by a notifiable disease.

Link to Australian Notifiable Disease list:

http://www.daff.gov.au/corporate_docs/publications/pdf/animalplanthealth/vetcom/nat_notif_dis_list05.pdf

5.6.11 Training and competency

- Resources and competence (Schedule 2, Clause 4.1), including knowledge, training, skills and experience.
- Particular consideration should be given to competence of staff responsible for control of Critical Control Points and/or critical operations.

The Approved Arrangement must provide details regarding how the occupier will ensure adequate resources and competence of staff that ensure the requirements of the *Export Control Act* and its' subordinate legislation is met. This should include training requirements for all staff with particular emphasis on those responsible for control of Critical Control Points and/or critical operations.

- The provision of resources

This should include a description of the establishment, equipment, materials, etc required for the activities to be carried out at the establishment and how they are to be sourced and maintained.

- The provision of personnel and their competence (including knowledge, training, skills and experience) – this should include information regarding the allocation of appropriately qualified staff and details about their competence, including how competence will be assessed and maintained.
- Responsibilities must be clearly identified to ensure effective implementation of the Approved Arrangement in a manner that guarantees compliance with legislative and importing country requirements.

Example:

The Approved Arrangement needs to document:

- The training needs for persons operating under the AA
- Details of what training is provided for new employees (including hygiene, function of the Approved Arrangement, HACCP, significance of export registration, what can and cannot be processed and how etc)
- Refresher training conducted for employees
- Training courses for supervisors and specialist positions eg:
 - Principles of Food safety
 - Development of HACCP plan
 - Pasteuriser operator
- Instructions and work procedures for employees
- Training in relation to specific importing country requirements documented in the Approved Arrangement
- Details on the frequency of training and how you assess competence of the employee
- How effectiveness of the program will be evaluated and at what frequency.

5.6.12 Miscellaneous

- Control and security of official marks and marking devices (Order 64)
- Alternative regulatory arrangements (Order 78)
- Penalty units and penal provisions

Control of official marks and official marking devices (Order 64) and security of official marks and marking devices (Order 68)

Where an occupier is in possession of an official mark or an official marking device (eg. an AQIS seal) the Approved Arrangement must include information about the controls in place for the use, possession and security of official marking devices.

In these circumstances the Approved Arrangement must identify:

- the person(s) who may have possession of the official marking device and
- the person(s) who may apply, alter or interfere with official marks and
- the controls in place for such activities (including security of official marks).

The occupier of an establishment must make a record of the receipt, use and return of official marking devices and the receipt, use and defacement of official marks.

Alternative regulatory arrangements (Order 78)

The *Export Control (Milk and Milk Products) Orders 2005* provides for alternative regulatory compliance. Under these arrangements the occupier of a Registered Establishment can make a written application to the Secretary for a notice stating that an alternative procedure, standard or other requirement specified in the application achieves the purpose of a requirement of Schedule 3 to 8 only of the *Export Control (Milk and Milk Products) Orders 2005* as specified in the application.

After reviewing the application, the Secretary may give the occupier a written notice to this effect.

If a notice is granted by the Secretary, the occupier must include in the Approved Arrangement:

- The procedure, standard or other requirement
- Detail how compliance with any alternative regulatory arrangement that has been approved by the Secretary, will be maintained.

Example:

Schedule 5 provides specific temperature requirements for chilling and freezing and allows for alternative temperature requirements provided that the Approved Arrangement validates that the alternative temperature and process will not affect the fitness for human consumption. (Schedule 5, Part 2)

5.6.13 Record keeping and documentation control

- Retention for 3 years
- Record keeping and documentation control

Requirement to retain documents (Schedule 2, Clause 10)

The occupier of the registered establishment must retain documents that provide evidence of compliance to the Act, Orders, approved arrangement for a minimum of three years.

Record keeping and documentation control

The Approved Arrangement must detail how the occupier will ensure that the approved arrangement is current and updated in accordance with the requirements to obtain approval from AQIS or the State Regulatory Authority. The system must provide evidence of changes to the system and that significant variations to the Approved Arrangement have been approved.

5.7 Importing country requirements (Schedule 2 clauses 2.1(c) and 2.2)

- The Approved Arrangement must document how specific importing country requirements, when appropriate, are met.
- Refer to www.aqis.gov.au/dairy

Importing country requirements are defined as requirements relating to milk and milk products that an importing country authority requires to be met before the goods may be imported into that country from Australia.

These could include: requirements that affect the method of processing, composition of food, methods of sampling and analysis, specific microbiological, residue or biotoxin requirements, alternative inspection arrangements, trade descriptions and other information that must appear on labels, design and construction matters for premises and equipment and food safety requirements for food processing.

The Approved Arrangement must document these importing country requirements where compliance with the Orders would not result in compliance with the importing country requirement i.e. the conditions may be higher or different. The Approved Arrangement must:

- Document the standard
- Detail how the product will comply
- Include any other procedures for ensuring the product is accurately identified throughout the process and segregated from other export product as compliance with a particular importing country standard may make the product ineligible for export to other markets.

Where an importing country requirement does not require compliance with a specific requirement in the *Export Control (Milk and Milk Products) Orders 2005*, the occupier can apply to the Secretary for a notice stating that a requirement of the *Export Control (Milk and Milk Products) Orders 2005* (specified in the application) does not apply to the milk and milk products prepared at the establishment to be exported to the country identified in the application.

The notice granting an alternative arrangement from a requirement of the *Export Control (Milk and Milk Products) Orders 2005* must be included in the Approved Arrangement along with details of the control measures used for identification and segregation of this product (Order 87) as the food may be made ineligible for domestic sale or export to other markets when a specific order is not met.

It is the occupiers' responsibility to be aware of the importing country requirements, however AQIS will assist where it is aware of specific requirements.

5.8 Export Permits and Government certificates (Order 53-60 and Schedule 9)

Refer to Guidelines for issue of export permits and government certificates

Where export documentation is issued from the export registered establishment the Approved Arrangement must document the measures that will be taken to ensure compliance with Part 5 of the *Export Control (Milk and Milk Products) Orders 2005*, namely the requirements to:

- Maintain export permits and government certificates under security.
- Return any revoked export permits and cancelled government certificate.
- Notify an authorized officer where there is suspicion that the fitness for human consumption of the food is jeopardised, or its security or integrity is compromised or an importing country requirement has not been met.
- Provide accurate and complete information.
- Provide all information required by Schedule 9 clause 2, provide an Exporter declaration of compliance, provide a copy of the export permit in 3 working

days, be signed by an appropriate person and contain information that is true and correct. (Order 59)

AQIS has developed guidelines/information sheets to assist you documenting your procedures including “ Export Documentation – A Guideline to Compliance with the *Export Control (Milk and Milk Products) Orders 2005*” and Declarations of compliance. These guidelines are available at www.aqis.gov.au/dairy.

Approval of Approved Arrangements for issuing permit

A person operating under an Approved Arrangement may issue an export permit if the Approved Arrangement provides for the issuing of export permits under documented systems. The person issuing the permit must be an approved permit issuer (accredited by AQIS) and be in management and control of the processing establishment which last prepared the food (i.e in EXDOC linked to the inspection establishment).

5.9 AQIS Approval process (including variations) Schedule 2 Clause 12-20

- Refer to Fact Sheet

5.10 Other:

- When operations other than preparation of milk and milk products for export must not occur at export establishments (Order 38)

Establishments that prepare milk and milk products for export must not undertake other activities (eg: preparation for domestic consumption or for animal food) unless the Approved Arrangement has appropriate controls in place. These controls must ensure either:

- Option1. That the fitness for human consumption of the milk and milk products for export is not put at risk; **and**
the identity of the milk and milk products for export is maintained separate from other product; **or**
- Option 2. That the ‘other activities’ are conducted in accordance with the requirements of the Act and the Orders ie the product is prepared in the same way as export product. (However, if importing countries require segregation and identification of product, then this must occur, eg for EU)

Currently AQIS regulates food for export but establishments may also wish to prepare food for the domestic market; in that case the Approved Arrangement will need to document how the product for domestic is to be handled to ensure compliance with the above, remembering that at all times export product must be able to be identified from purely domestic product.

Example:

Option 1 – Separation of product detailed in the Approved Arrangement

Option 1 (a) domestic product

If a Registered Establishment produces dairy product for export and also for the domestic market, the Approved Arrangement must detail how the establishment ensures that the domestic product does not put at risk the product produced for export with clear segregation of domestic and export eligible product.

Option 1 (b) animal food

If a Registered Establishment produces dairy product for export and also for animal food, the Approved Arrangement must detail how the establishment ensures that the animal food does not put at risk the product produced for export. The Approved Arrangement must clearly indicate the procedures that ensure export product is fit for human consumption without contamination by the animal food including appropriate segregation procedures, labelling of animal food and the procedures that ensure that animal food is never incorporated into product for human consumption.

Option 2 – all products “export eligible”

If a Registered Establishment produces dairy product for export and also for the domestic market, the Approved Arrangement must include controls to meet all requirements for export during all production runs and cover all product produced at the establishment for all product to be export eligible.

6.0 Summary checklist

Components of an Approved Arrangement	Comments
<p>Introduction</p> <ul style="list-style-type: none"> • Scope & purpose of the Approved Arrangement 	
<p>Management & Establishment details</p> <ul style="list-style-type: none"> • Establishment number • Management & contact details • Identification of products produced at the establishment 	
<p>Management Practices (Orders 36-38 and Schedule 2)</p> <ul style="list-style-type: none"> • Occupiers commitment (Schedule 2, Clause 1.1) • Management practices, organisational structure • Communication – with AQIS, SRAs – obligation to notify 	
<p>HACCP Plan</p> <p>Minimum requirements see Schedule 2; clause 2.1</p> <p>The HACCP plan (Schedule 2; clauses 3.1-3.8) must identify:</p> <ul style="list-style-type: none"> • Each of the steps in the preparation of the food (a flow chart may be used); and • The potential hazards that may reasonably be expected to occur; and • The means of control of each potential hazard; and • The critical control points (CCP) for each significant hazard; and • The critical limit that must be met for each critical control point; and • The procedures used to monitor the significant hazards to ensure compliance with each critical limit including: <ul style="list-style-type: none"> ◦ The frequency at which monitoring procedures will be performed; and ◦ The person/persons (including a class of persons) who will carry out these procedures; and • The corrective action to be taken if a critical limit is exceeded; and • Verification and validation procedures (Schedule 2, Clause 6.1); and • The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness. <p><i>Key areas of consideration:</i></p> <ul style="list-style-type: none"> • Sourcing (Schedule 5, Part 1) including raw milk & on farm requirements, ingredients and raw materials of dairy and non dairy origin • Chilling, freezing and thawing (Schedule 5, Part 2) • Preserving milk and milk products including pasteurisation (Schedule 5, Part 3) • Packaging (Schedule 5, Part 4) • Transport (Schedule 5, Part 6) • Fitness for human consumption (Schedule 5, Part 7) 	
<p>Verification and Validation</p> <ul style="list-style-type: none"> • Verification (Schedule 2, Clause 6.1) 	

Components of an Approved Arrangement	Comments
<ul style="list-style-type: none"> • Internal audit and management review (Schedule 2, Clause 8.1 & 8.2) • Validation (Schedule 4, Clause 12.1 & Schedule 5, Clauses 4 – 10 & 16 & 17) <p><i>Product standards & testing (Order 50 and Schedule 6)</i></p> <ul style="list-style-type: none"> • Analysis of samples to substantiate certification claims (Order 103) • Product standards for food and ingredients (Schedule 6, Part 1) • Contaminants, natural toxicants, residues and food additives (Schedule 6, Clause 1) • Microbiological limits (Schedule 6, Clause 2) • Methods of sampling and examination (Schedule 6, Part 2) • Sampling and analysis (Schedule 2, Clause 9.1 & 9.2) 	
<p>Support Programs (Orders 39.1 (b), 47,48 and Schedule 3 and 4)</p> <p><i>Sourcing</i></p> <ul style="list-style-type: none"> • Raw milk • Dairy products as ingredients, including imported ingredients • Non-dairy ingredients, including imported ingredients <p><i>Hygiene</i></p> <ul style="list-style-type: none"> • Cleaning and sanitising of premises, equipment and transport vehicles (Schedule 3, Clause 12, 13) (Schedule 4, Clause 2-4) • Pest control program (Schedule 4, Clause 7) <p><i>Good Manufacturing Practice</i></p> <ul style="list-style-type: none"> • Use and storage of hazardous substances (Schedule 4, Clauses 8, 9) • General controls for storage of food, including protection from contamination, storage, handling and transportation (Schedule 4, Clause 10) <p><i>Equipment & Premises</i></p> <ul style="list-style-type: none"> • Maintenance of establishments and equipment (Schedule 4, subclause 3.5) to ensure that milk and milk products for export as food are prepared in an establishment that complies with the applicable requirements of Schedule 3 (Structural requirements) Order 47 • Calibration of measuring equipment (Schedule 4, Clause 11) <p><i>Food Handling</i></p> <ul style="list-style-type: none"> • Control for ingredients including fitness for purpose, labelling, storage and handling (Schedule 4, Clause 13) • Water usage and testing including chilled water (Schedule 4, Clause 14, 15, 17, & 18) • Use of compressed air and other gases (Schedule 4, Clause 19) • By-products & reworked product • Presence of potentially harmful substances (Schedule 5 clause 1.1) <p><i>Personal Practices</i></p> <ul style="list-style-type: none"> • Personal hygienic and health requirements (Schedule 4, Clause 20-25) <p><i>Maintenance of currency of Registration details (Orders 33 & 34 & 42 and Schedule 1 and Part 4 of Export Control (Prescribed Goods General) Orders [PGGOs])</i></p> <ul style="list-style-type: none"> • Milk and milk products must be prepared in a registered establishment or an approved unregistered establishment (Orders 33 	

Components of an Approved Arrangement	Comments
<p>and 34)</p> <ul style="list-style-type: none"> • Plans and specifications (Part 1 Schedule 1) • Registration requirements (Order 4.04 PGGOs) • Certificate to be displayed (Order 4.10 PGGOs) • Changes of which Secretary must be notified (Division 4.4 PGGOs) • Alterations or additions (Division 4.5 PGGOs) • Variation of export operations (Division 4.6 PGGOs) <p><i>Trade description (Order 51 and Schedule 7)</i></p> <ul style="list-style-type: none"> • Contents of the trade description (Schedule 7 Part 2) • Requirement to provide translations (Order 84) • Requirements to comply with the Trade Practices Act (Schedule 7 Part 2) <p><i>Identification, tracing systems, integrity and transfer (Order 52 and Schedule 8)</i></p> <ul style="list-style-type: none"> • Identification and tracing systems (Schedule 8 Part 1) including Production records (Schedule 8 clause 5) • Sourcing raw milk, milk products for further manufacture and other ingredients (Schedule 8 clause 4.1) • Transfer of milk and milk products (Schedule 8 Part 3) • Declaration of Compliance (Schedule 9 Division II) <p><i>Control of nonconforming product</i></p> <ul style="list-style-type: none"> • Hold and/or release procedures • Product recall • Notification to regulatory authorities • Preventative action (Schedule 2, Clause 7.2) <p><i>Training and competency</i></p> <ul style="list-style-type: none"> • Resources and competence (Schedule 2, Clause 4.1), including knowledge, training, skills and experience. • Particular consideration should be given to competence of staff responsible for control of Critical Control Points and/or critical operations. <p><i>Miscellaneous</i></p> <ul style="list-style-type: none"> • Control and security of official marks and marking devices eg AQIS seals (Order 76) • Alternative regulatory arrangements (Order 86) <p><i>Record keeping and documentation control</i></p> <ul style="list-style-type: none"> • Retention for 3 years • Plans and specifications and approval of variations to establishments • Certification of registration • Record keeping and document control (Schedule 2, Clause 11) 	
<p>Importing country requirements (Schedule 2 clauses 2.1(c) and 2.2)</p> <ul style="list-style-type: none"> ▪ Product made to meet specific importing country requirement must be documented in the approved arrangement and should include details of standards, labelling, storage conditions etc. ▪ Refer to www.aqis.gov.au/dairy 	
<p>Export Permits and Government certificates (Order 53-60 and Schedule</p>	

Components of an Approved Arrangement	Comments
9) <ul style="list-style-type: none"> • Refer to Guidelines for issue of export permits and government certificates 	
AQIS Approval process (including variations) Schedule 2 Clause 12-20 <ul style="list-style-type: none"> • Refer to Fact Sheet 	
Other: <ul style="list-style-type: none"> • When operations other than preparation of milk and milk products for export must not occur at export establishments (Order 38) 	

7.0 Guidelines and References:

AQIS has developed a series of “Guidelines to Compliance with the *Export Control (Milk and Milk Products) Orders 2005*” to assist you with compliance with various aspects of the new legislation. They will discuss what needs to be done and provide examples to assist you.

Guidelines can be accessed at www.aqis.gov.au/dairy

AQIS has developed separate documents providing details of comparisons of requirements for FPA, AQA and the Food Standards Code with the requirements for Approved Arrangements as follows:

- Self Assessment Checklist for Approved Arrangements
- Comparison of the Approved Arrangement with an Approved Quality Assurance (AQA) arrangement
- Comparison of the Approved Arrangement with an Food Processing Accreditation (FPA) system
- Comparison of the Approved Arrangement with the Food Standards Code (FSC) Food Safety Plan

Information sheets regarding Compliance with the *Export Control (Milk and Milk Products) Orders 2005* include:

- Approved Arrangement checklist for manufacturing establishments
- Approved arrangement checklist and guidelines for stores
- Validation and Verification
- Traceability
- Trade Description
- Export Documentation
- Declarations of compliance
- Approved transfer systems
- Information sheet on Schedules 2, 3, 4, 5, 6, 7, 8, 9
- Information regarding becoming export registered
- Information you need to know prior to exporting

ANZDAC* has developed documents that also provide guidance to complying with legislative requirements. These include:

- ANZDAC Minimum Sampling Guidelines
- Australia New Zealand Dairy Authorities' Standards Committee (ADASC) Listeria Manual
- ADASC Salmonella Manual
- ANZDAC Validation and Verification of Heat Treatment Equipment and Processes
- Other references include:
 - Codex references:
 - Australian Standards:

* Note: ADASC is the predecessor committee to ANZDAC and was responsible for the development of the Listeria and Salmonella Manuals referenced.

8.0 Forms

Model Application Form for an Approved Arrangement