



Australian Government

Australian Quarantine and Inspection Service

# **Approved Arrangement**

*For establishments that store and or load dairy products for  
export purposes*

**A Guideline to Compliance with the**

***Export Control (Milk & Milk Products) Orders  
2005***

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## **1.0 Background**

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

The guideline services to provide 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.

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. The Approved Arrangement requires occupiers to demonstrate a commitment to food safety principles through documented procedures, Good Manufacturing Practice (GMP) and hygienic practices to ensure that food safety outcomes are met.

The guideline serves to provide 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.

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

## **2.0 Minimum Requirements for an Approved Arrangement**

The safety of dairy products has and continues to attract international attention from both consumers and importing government authorities.

This raises the need for food destined for export to be managed under systems that effectively control the hazards that can compromise food safety and which will provide a sound basis for AQIS to issue government to government assurances in export certification.

AQIS has the responsibility for ensuring that the systems implemented in Australia result in the production of dairy products that are safe to eat and as free as possible from hazards that are potentially harmful to humans.

Industry compliance with Approved Arrangements and AQIS's system of approving and monitoring them through audit contributes to importing country confidence that Australian food is safe, suitable, accurately described, traceable and meets their requirements to be eligible for importation.

### **3.0 Why is an 'Approved Arrangement' required?**

Export Control (Milk & Milk Products) Orders 2005 - Part 4 - Order 44

#### **44 Requirement for an approved arrangement**

**44.1** Processed food for export as food must be prepared in an establishment where the occupier has an approved arrangement that covers the preparation undertaken.

The Approved arrangement is a mandatory condition of exporting dairy products from an AQIS registered establishment.

### **4.0 Who needs an 'Approved Arrangement'?**

This includes occupiers of all AQIS establishments registered for producing milk and milk products and includes establishments that store and load dairy products for export

### **5.0 What is an 'Approved Arrangement'?**

An Approved Arrangement is a documented system of controls that will be approved by AQIS for the preparation and storage of food at each individual export Registered Establishment.

Export Control (Milk & Milk Products) Orders 2005 - Order 8

#### **8 Interpretation**

*approved arrangement* means an arrangement approved under clause 14 of Schedule 2 and includes a variation of an arrangement in the circumstances specified in suborder 86.5 and clause 20 of Schedule 2

The Approved Arrangement must show how the relevant conditions and restrictions set out in the Orders will be complied with by each Establishment.

The purpose of the Approved Arrangement is to provide assurance to AQIS through an auditable system that the food is prepared and stored in such a way as to:

- Meet the minimum requirements for Approved Arrangements (subclause 2.1 of Schedule 2); and
- Demonstrate that compliance with the controls specified in the Approved Arrangement will ensure that the objectives and applicable requirements of the Orders will be complied with; and
- Ensure the importing country requirements specified in the Approved Arrangement for the food will be complied with; and
- Provide a sound basis for giving export permits and for issuing government certificates.

Industry compliance with Approved Arrangements and AQIS's system of approving and monitoring them through audit contributes to importing country confidence that Australian

food is safe, suitable, accurately described, traceable and meets their requirements to be eligible for importation.

## **6.0 Components of the Approved Arrangement**

An Approved Arrangement must document as a minimum the following requirements. The following checklist has been designed to assist in ensuring you cover each component in the Approved Arrangement before making an application to AQIS for approval of the documented Approved Arrangement.

## **7.0 Summary checklist**

<b>Components of an Approved Arrangement</b>
<ul style="list-style-type: none"> <li>• Registration requirements (Order 4.04 PGGOs)</li> <li>• Certificate to be displayed (Order 4.10 PGGOs)</li> <li>• Changes of which Secretary must be notified (Division 4.4 PGGOs)</li> <li>• Alterations or additions (Division 4.5 PGGOs)</li> <li>• Variation of export operations (Division 4.6 PGGOs)</li> </ul>
<p><b>EC(M&amp;MP)Os: Management Practices (Orders 36-38 and Schedule 2)</b></p> <ul style="list-style-type: none"> <li>• Occupiers commitment (Sch 2, Clause 1.1)</li> <li>• Management practices, organisational structure, resources and competence (Sch 2, Clause 4.1)</li> <li>• Verification (Sch 2, Clause 5.1)</li> <li>• Corrective and preventative action (Sch 2, Clause 6.1 &amp; 6.2)</li> <li>• Internal audit and management review (Sch 2, Clause 7.1 &amp; 7.2)</li> <li>• When operations other than storing of processed food for export must not occur at export establishments (Order 38)</li> <li>• Requirement to retain documents for a minimum period (Sch 2, Clause 10.1)</li> </ul>
<p><b>EC(M&amp;MP)Os: Structural requirements (Order 39 and Schedule 3)</b></p> <ul style="list-style-type: none"> <li>○ Processed food for export as food must be stored in an establishment where there is compliance with the applicable requirements of Schedule 3 (Structural requirements) Order 47</li> <li>○ Food carrying compartments, container systems units and vehicles (Sch 3, clause 9.1)</li> <li>○ Cleaning and sanitising facilities (Sch3, Division II)</li> <li>○ Amenities (Sch3, Division III)</li> <li>○ Essential Services (Sch3, Division IV)</li> </ul>
<p><b>EC(M&amp;MP)Os: Hygiene Control Programs (Support Programs, Pre-requisite Programs, GMP)</b> <b>(Orders 39.1 (b), 47,48 and Schedules 3 and 4)</b></p> <ul style="list-style-type: none"> <li>• Cleaning and sanitising of premises, equipment and transport vehicles (Sch 3, Clause 12,13) (Sch 4, Clause 2-4)</li> <li>• Maintenance of establishments and equipment (Sch 4, Clause 3.5)</li> <li>• Measures to prevent environmental contamination (including water borne and air borne contamination) (Sch 4, Clause 5)</li> <li>• Exclusion of animals (Sch 4, Clause 6)</li> <li>• Pest control program (Sch 4, Clause 7)</li> <li>• Use and storage of hazardous substances (Sch 4, Clause 8,9)</li> </ul>

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<p><b>EC(M&amp;MP)Os:</b></p> <ul style="list-style-type: none"> <li>• General controls for storage of food, including protection from contamination, storage, handling and transportation (Sch 4, Clause 10)</li> <li>• Calibration of measuring equipment (Sch 4, Clause 11)</li> <li>• Validation of refrigeration chambers (Sch 4, Clause 12)</li> </ul>
<p><b>EC(M&amp;MP)Os: Specific requirements (Order 49 and Schedule 5)</b></p> <ul style="list-style-type: none"> <li>• Chilling, freezing, thawing and tempering (Sch 5, Part 2)</li> <li>• Packaging (Sch 5, Part 4)</li> <li>• Storage, handling and loading (Sch 5, Part 5)</li> <li>• Transport (Sch 5, Part 6)</li> <li>• Fitness for human consumption (Sch 5, Part 7)</li> </ul>
<p><b>EC(M&amp;MP)Os: Identification, tracing systems, integrity and transfer (Order 52 and Schedule 8)</b></p> <ul style="list-style-type: none"> <li>• Identification, tracing systems and recall (Sch 8 Part 1)</li> <li>• Sourcing processed food (Sch 8 clause 4.1)</li> <li>• Transfer of processed food (sch 8 Part 3)</li> </ul>
<p><b>EC(M&amp;MP)Os: Miscellaneous</b></p> <ul style="list-style-type: none"> <li>• Manufacture etc of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)</li> <li>• Alternative regulatory arrangements (Order 86)</li> </ul>
<p><b>EC(M&amp;MP)Os: Importing country requirements (Schedule 2 clauses 2.1(c) and 2.2)</b></p> <ul style="list-style-type: none"> <li>▪ <b>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.</b></li> </ul>
<p><b>EC(M&amp;MP)Os: Export Permits and Government certificates (Order 53-60 and Schedule 9)</b></p> <ul style="list-style-type: none"> <li>• Maintain permits and government certificates under conditions of security. (Order 55)</li> <li>• Return any revoked export permits, cancelled government certificate. (Order 56)</li> <li>• 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. (Order 57)</li> <li>• Provide accurate and complete information. (Order 58)</li> <li>• Provide all information required by Schedule 9 Clause 2, provide a 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. (See Schedule 9 and Order 59)</li> <li>• Record keeping (Order 60)</li> </ul>
<p><b>EC(M&amp;MP)Os: Approval process (including variations) Schedule 2 Clause 12-20</b></p> <ul style="list-style-type: none"> <li>• Application (Sch 2, Clause 12)</li> </ul>

<b>Components of an Approved Arrangement</b>
<ul style="list-style-type: none"> <li>• Registration requirements (Order 4.04 PGGOs)</li> <li>• Certificate to be displayed (Order 4.10 PGGOs)</li> <li>• Changes of which Secretary must be notified (Division 4.4 PGGOs)</li> <li>• Alterations or additions (Division 4.5 PGGOs)</li> <li>• Variation of export operations (Division 4.6 PGGOs)</li> </ul>
<p><b>EC(M&amp;MP)Os:</b></p> <ul style="list-style-type: none"> <li>• Desk audit (Sch 2, Clause 13)</li> <li>• On site audit (Sch 2, Clause 13)</li> <li>• Variations to an approved arrangement (Sch 2, Clause 17-20)</li> </ul>

### **8.0 AQIS Guidelines:**

AQIS has developed a series of “Guidelines to Compliance with the *Export Control (Milk and Milk Product) 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 obtained from <http://www.aqis.gov.au/dairy>

**Guidelines to Compliance with the *Export Control (Milk and Milk Product) Orders 2005* include:**

- Approved arrangement checklist and guidelines for stores
- Traceability
- Declarations of compliance
- Approved transfer systems
- Information sheet on Schedule 2, 3, 4, 5, 6, 7, 8, 9
- Information regarding becoming export registered
- Information you need to know prior to exporting

### **9.0 Comparison of components of the Approved Arrangement with FPA/AQA**

To give you an indication of the major changes in the Orders, comparisons of the Approved Arrangement to a traditional Food Processing Accreditation (FPA) included in Attachment 1 and 2 respectively.

For assistance in what information has to be documented in the Arrangement see the checklist Attachment 3 which goes into each component separately and gives you examples on how to comply.

### **10.0 How to apply for an Approved Arrangement**

All Approved Arrangements must be evaluated by AQIS to determine if the Arrangement complies with subclause 2.1 of Schedule 2 of the EC(M&MP)Os and that compliance with the controls specified in the Arrangement will ensure that the applicable requirements of the Orders will be complied with, that importing country requirements specified in the arrangement will be complied with and that there is a sound basis for giving an export permit or issuing a government certificate.

When all components of an Arrangement have been documented and implemented the company may then apply for approval of the Arrangement.

Initially a desk audit will be conducted to evaluate the system. When AQIS is satisfied that all the relevant requirements have been appropriately addressed in the Approved Arrangement, a site audit will be conducted.

The purpose of this audit is to ensure that the procedures documented in the Approved Arrangement are being followed and are effective in practice. The initial audit findings, recommendations and any requests for further information will be provided to the Establishment for rectification. Once non-compliances have been rectified / addressed and a reassessment carried out, the Approved Arrangement will be approved by the Secretary (or delegate of the Secretary) and a notice will be provided to formalise the arrangement.

#### **Variations to be recorded**

The occupier must make a record of each variation of an Approved Arrangement. This may be in the form of a table setting out the amendment history.

Significant variations that impact directly upon compliance with the Orders must be approved before they are implemented.

**Attachment 1:****Comparison of the Approved Arrangement with a Food Processing Accreditation (FPA)**

While the FPA system contains many of the components of an Approved Arrangement – this table indicates which components were not previously required or were not required to be documented under an FPA arrangement. Under an Approved Arrangement – all components listed must now be documented and implemented and existing documentation carefully reviewed to ensure compliance with the new Orders

<b>Component of an Approved Arrangement</b>		<b>F P A</b>	<b>Comments</b>
<b>Management Practices</b>	Occupiers commitment	Y	Was covered in Schedule 7, 9.1(e) Export Control (Processed Food) Orders
	Management practices, organisational structure, resources and staff training	N	See Attachment 3 – Management Practices
	Verification	N	See Attachment 3 & Verification & Verification Guideline
	Corrective and preventative action	Y	Records must be kept of all Corrective Action taken. See Attachment 3 – Management Practices
	Internal audit and management review	N	See Attachment 3 – Internal Audit
<b>Hygiene Control Programs (GMP)</b>	Cleaning and sanitising of premises, equipment and transport vehicles	N	Required to have a cleaning program, now it must be documented.
	Maintenance of establishments and equipment	N	While all Hygiene Control Programs listed were required to be complied with under an FPA – there is now a requirement that an Establishment documents the controls used to ensure that the applicable requirements of the Orders are complied with. (Sch 2, Div II)
	Measures to prevent environmental contamination	N	
	Exclusion of animals	Y	Was covered in Sch3 – Clause 7.1 Export Control (Processed Food) Orders
	Pest control program	Y	Previously required
	Use and storage of hazardous substances	N	Not previously required
	General controls for storage of food, including protection from contamination, storage, handling and transportation	N	Not previously required to be documented
	Calibration of measuring equipment eg Coolrooms, freezers etc	N	Not previously required to be documented
	Validation of refrigeration chambers	N	Required to monitor and record temp daily as GMP
	Control for ingredients including fitness for purpose, labelling, storage & handling	N	Not previously required to be documented
Personal hygienic and health requirements	N	Not previously required to be documented	
<b>Specific Requirements (Schedule 5)</b>	Chilling, freezing, thawing and tempering (Part 2)	N	While required to be complied with under an FPA – there is now a requirement that an Establishment documents the controls used to ensure that the applicable requirements of the Orders are complied with. (Sch 2, Div II). See Attachment 3
	Storage, handling and loading (Part 5)	N	
	Transport (Part 6)	N	
	Fitness for human consumption (Part 7)	N	
<b>Trade Description</b>	See Schedule 7 of the EC (M&MP) Os 2005 for details	N	See Attachment 3 - Trade Description & Trade Description Guideline for further information

Component of an Approved Arrangement		F P A	Comments
(Schedule 7)			
<b>Identification, tracing systems, integrity &amp; transfer (Sch 8)</b>	See Schedule 8 of the EC (M&MP) Os 2005 for details	N	EU estab should have systems documented. See Traceability Guideline for information regarding Transfer Certificates & Declarations of Compliance
<b>Miscellaneous</b>	Manufacture etc of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)	N	Refer EC (M&MP) Os – Part 7 – Orders 72 & 76
	Alternative regulatory arrangements (Order 86)	Y	Schedule 7 6.1 EC (M&MP) Os although not previously documented in FPA
<b>Export permits &amp; Government Certificates</b>	Maintain permits and government certificates under conditions of security	Y	For further information on this section see Export Documentation Guideline
	Return any revoked export permits, cancelled government certificate.	Y	
	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.	N	EC (M&MP) Os – Order 57
	Provide accurate and complete information.	Y	
	Provide all information required by Schedule 9 clause 2, provide a 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)	Y	All previously required, except now additional requirements of Schedule 9, 3.1 EC (M&MP) Os.
	Approval process (including variations)		
	Record keeping		EC (M&MP) Os – Order 60
<b>Approval process (including variations)</b>	Application	Y	
	Desk audit	Y	
	On site audit	Y	
	Variations to an approved arrangement	Y	EC (M&MP) Os – Schedule 2 – Clause 17 - 20

## **Attachment 3: Assistance with Documenting the Approved Arrangement**

### **I Minimum Requirements for Approved Arrangements for a storage establishment**

The *Export Control (Dairy, Eggs and Fish) Orders 2005* details in broad terms the minimum requirements for an approved arrangement, as follows:

Export Control (Milk & Milk Products) Orders 2005 – subclause 2.1 – 2.2 – Schedule 2

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#### **Schedule 2**

- a) document the controls used to ensure that the applicable requirements of these Orders (other than a requirement of Schedule 3) are complied with at the establishment; and
- b) identify any applicable importing country requirements and document the controls used to ensure compliance with these requirements; and
- c) document any other measures necessary to ensure there is a sound basis for giving any export permit or issuing any government certificate for processed food prepared at the establishment

2.2 Paragraphs 2.1(b) applies only to each importing country requirement for which compliance with these Orders would not be sufficient to result in compliance with the importing country requirement.

The following information is aimed at providing you with details of what you must do to comply with the minimum requirements.

As some of the concepts in the new legislation may be new to you, AQIS has developed a series of guidelines that should be read in conjunction with this document to give you a better understanding of requirements.

#### **Schedule 1 – Registration**

Schedule one provides the mechanism for the requirements of Part 3, Orders 33-35 of the *Export Control (Milk & Milk Products) Orders 2005* and detail's the requirements of plans and specifications, of premises that are required to be submitted when applying to be registered as an export dairy establishment, also the requirements of plans and specifications necessary for alterations and additions. Schedule 1 also outlines the requirements for approval to prepare processed food in an unregistered establishment.

Export Registration Certificate:

The approved arrangement should ensure that the details for the registered establishment are current including key personnel, contact details, and any specific importing country approvals as appropriate.

Hyper-[Link to Registration Information Sheet](#)

Plans :

The approved arrangement should ensure that current plans are maintained and available for auditors and importing country reviewers. This includes water and equipment details.

## II Schedule 2 - Management Practices

There is a range of responsibilities, which although not being new to occupiers of Establishments, which have been operating on Approved Quality Assurance arrangements, may be new to those previously operating a Food Processing Accreditation. It is important that you understand the legal responsibilities that you have and are aware that there are penalties associated with non-compliance.

### Occupier's commitment

The occupier of an establishment used to store processed food for export must make a statement in the Approved Arrangement, which commits the occupier to meeting:

1. The objectives of the Orders;
2. Compliance with the requirements of the Orders; and
3. Compliance with any applicable importing country requirements. (Sch 2, clause 1.1)

### Management practices, organisational structure, resources and competence

Export Control (Milk & Milk Products) Orders 2005 2005 – subclause 4.1 – Schedule 2

#### Schedule 2

- 4.1 The management practices, organisational structure, provision of resources and the provision of personnel must:
- (a) be documented
  - (b) be appropriate to ensure each of the following are met:
    - (i) the applicable requirements of the 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:

- Make a statement which describes and endorses 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 should also include:

- A statement on the organisation's objectives, including performance improvement and commitment to maintaining product integrity and the storage 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

- 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)

**Example:**

The AA 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, significance of export registration)
- Refresher training conducted for employees
- 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

## Verification

The occupier must document how he/she verifies compliance with Export Control (Milk & Milk Products) Orders 2005:

- The requirements of Division III of Part 3 of the Orders; and
- Any identified importing country requirements.
- The results of all verification activities must be recorded (Schedule 2, clause 6)

**Verify** means apply methods, procedures, tests and other evaluations in addition to monitoring to determine whether a requirement is complied with.

## Export Control (Milk & Milk Products) Orders 2005 – Order 39

### Part 3 Division III

39.1 The occupier of an establishment engaged in the preparation of processed food must ensure that the applicable requirements of the following Schedules are met:

- (a) Schedule 3 – Structural requirements
- (b) Schedule 4 – Operational hygiene
- (c) Schedule 5 – Preparation and transport
- (d) Schedule 6 – Product standards
- (e) Schedule 7 – Trade descriptions
- (f) Schedule 8 – Identification, tracing systems, integrity and transfer

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 made to ensure that each of the requirements in the Schedules listed above are complied with.

AQIS has developed guidelines to assist you in documentation of Schedule 6, 7 and 8. These can be found on the following website [www.aqis.gov.au/dairy](http://www.aqis.gov.au/dairy).

Examples are given in the guidelines that may be of relevance to your operations. The requirements for compliance with the other schedules will be discussed in Attachment 3 of this document.

For example, the Approved Arrangement may have separate sections, which addresses how the occupier is going to manage the operations under these schedules from a day-to-day perspective. The management is responsible for checking that all of the operations are being conducted in accordance with the documented system so that they are able to make the statement that the product complies with the Orders. Please refer back to the Summary Checklist for items included in each of these schedules.

### **Corrective and preventative action**

The Approved Arrangement must include a record of all action taken (corrective or preventative) where a requirement of any of the above Schedules in Division III, Part 3 of the EC(M&MP)Os is not complied with or not likely to be complied with.

The action taken must:

- Address the non-compliance
- Ensure that the failure will not recur; and
- Assess the effectiveness of the action taken (Schedule 2, clause 7).

### **Internal audit and management review**

The Approved Arrangement must document procedures for internally auditing your own Arrangement and conducting management reviews.

To ensure on-going compliance with legislative requirements and the practices carried out under the Approved Arrangement it is necessary for you to audit the Approved Arrangement to identify if everything is running smoothly, to identify any changes in the system, changes to operations, failure of staff to maintain the systems or to identify any activities which are not being complied with which could impact on the preparation of safe and suitable food.

It is part of good management that you know what, if anything is going wrong so you can be proactive in putting it right.

You need to review your Arrangement to ensure that what you are doing is consistent with what you say you are doing and that the operations are planned and not haphazard and uncontrolled.

***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 audit 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.

Management review should include an assessment of the entire Approved Arrangement and take into consideration findings from internal reviews conducted by you or your staff and external reviews carried out by AQIS or any other organisation looking at your food safety system.

***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:

- Have a defined agenda
- Be undertaken by nominated responsible personnel eg senior management and QA staff
- Records of the meetings must be kept
- Review internal and external audit outcomes
- Overseas review outcomes (if relevant), 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 on-going compliance of the Approved Arrangement to meet legislative requirements.

Internal audit and management review must be

- Conducted at least once every twelve months
- Records of reviews and audits must be maintained.

*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 8).

### **Requirement to retain documents**

The occupier of the Registered Establishment should familiarise themselves with Schedule 2 Clause 11 which relates to the requirement to retain documents for a minimum of three years which comes into their possession or are made in the process of complying with the requirements of the Act, Orders, Approved Arrangement and importing country requirements identified in the Approved arrangement.

### **When operations other than preparation of processed food for export must not occur at export establishments (Order 38)**

Establishments that store processed food for export must not undertake other activities (eg: storage for domestic consumption or for animal food) unless the approved arrangement has appropriate controls in place. These controls must ensure either:

- Option 1. The fitness for human consumption of the processed food for export is not put at risk; **and**  
The identity of the processed food for export is maintained separate from other product; **or**
- Option 2. The 'other activities' are conducted in accordance with the requirements of the Act and the Orders i.e 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 EU)

Currently AQIS regulates food for export but Establishments may also wish to store food for the domestic market in which 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 that export product must be able to be identified from purely domestic product.

### **III Schedule 3 - Structural requirements**

Schedule 3 covers the structural requirements that Establishments must meet in order to store milk and milk products as food for export.

In general, the assessment of the premises, cleaning and sanitising facilities and are part of the AQIS registration process of the Establishment, as without ensuring appropriate facilities are available to store the food for export, the facilities themselves may present a major hazard to safe production of food.

When you register for export the AQIS authorised Officer will request plans of the Establishment and inspect your premises; this registration inspection is designed to provide you with information as to whether the premises complies with requirements or whether upgrades are required before operations commence. Registration will not occur until the premises meet requirements.

The occupier must maintain the premises in accordance with the requirements of Schedule 3. Schedule 4 Clause 3.5, which requires the premises and equipment, is maintained in a state of good repair. You do not need to document this in an Approved Arrangement but you will need to advise AQIS of any changes to structural requirements that you wish to make after you are registered, as follows:

Export Control (Milk & Milk Products) Orders 2005 – subclause 3.1 – 3.2 – Schedule 3

**Construction must comply with plans and specifications**

3.1 The construction of the premises and equipment must, in the case of registered establishments, comply with the plans and specifications in relation to which the Secretary registers the establishment.

3.2 Alterations or additions for which a proposal is required under Division VII of Part 5 of the Prescribed Goods (General) Orders 1985 must comply with the plans and specifications in relation to which approval for the proposal is given.

Note: For plans and specifications see Part 1 of Schedule 1.

In addition, your Approved Arrangement should detail how you intend to verify compliance with Schedule 3 eg. by periodic internal audit of premises and equipment.

There are some guiding principles that should be considered when constructing premises that are given in Schedule 3 clause 2.1

Export Control (Milk & Milk Products) Orders 2005 – subclause 2.1 Schedule 3

2.1 The premises and their construction must:

- (a) facilitate the storage of processed food that is fit for human consumption; and
- (b) be fit for the purpose for which they are used; and
- (c) have sufficient capacity for the maximum quantity of processed food stored at the premises at any one time; and
- (d) permit the premises to be effectively cleaned and, if necessary, sanitised if there is a risk they may cause contamination of processed food; and
- (e) permit the premises to be effectively accessed, inspected and monitored; and
- (f) not permit the harbourage of pests; and
- (g) to the extent that is practicable:
  - (i) exclude dirt, dust, fumes, smoke and other contaminants; and
  - (ii) not permit the entry of pests; and
  - (iii) minimise the accumulation of contaminating substances.

So whether construction is of the floors, walls, ceiling, equipment, fixtures or fittings, the above principles apply. See Schedule 3 Clauses 5-8 for more information.

#### **IV Schedule 4 – Operational Hygiene**

Export Control (Milk & Milk Products) Orders 2005 – Order 48

**Order 48 - Operational Hygiene** states:

Processed food for export as food must:

- (a) be prepared/stored at an establishment where there is compliance with the applicable requirements of Schedule 4 (Operational hygiene); and
- (b) be transported to and from establishments engaged in the preparation/storage of the processed food using vehicles and equipment that comply with the applicable requirements of Schedule 4 (Operational hygiene).

A program of operational controls for the hygienic preparation/storage of processed food must be documented and in place at the premises used to prepare/store processed food. (Schedule 4, clause 1.1) These controls are often called Pre-requisite programs, Support programs or Good Manufacturing Practices (GMPs).

Pre-requisite programs are documented systems detailing the operational controls in place for hygienic preparation/storage of food. If general hygiene and sanitation in an Establishment is not controlled then it has the potential to influence the food safety status of the product.

These operational controls should include routine procedures covering:

- Cleaning, sanitising and ongoing maintenance of premises, equipment and transport vehicles (Schedule 4, clauses 2, 3 & 4)
- Exclusion of animals from premises (Schedule 4, clause 6)
- Pest control program (Schedule 4, clause 7)
- Use and storage of hazardous substances (Schedule 4, clauses 8 & 9)
- General controls for processed food and ingredients, including protection from contamination, storage, handling and transportation (schedule 4, clause 10)
- Calibration of measuring equipment (Schedule 4, clause 11)
- Validation of refrigeration chambers (schedule 4, clause 12)
- Personal hygienic and health requirements (Schedule 4, clauses 20 – 25)

## VI Schedule 5 Preparation and Transport

Export Control (Milk & Milk Products) Orders 2005 – Order 49

**Order 49 - Preparation and Transport** states:

Processed food for export as food must:

- (a) be prepared/stored; and
  - (b) be transported to and from establishments engaged in the preparation/storage of the processed food;
- in accordance with the applicable requirements of Schedule 5 (Preparation and transport).

### 2. Chilling, freezing, thawing and tempering (Schedule 5, Part 2)

The Approved Arrangement must document how the temperature controls nominated in the Orders for chilled and frozen product are adhered to for all processed food during storage, handling, loading and transport.

Export Control (Milk & Milk Products) Orders 2005 – subclause 25.1 – 25.4 – Schedule 5

#### **Rate of Chilling**

- 25.1 The chilling of processed food must be performed with sufficient rapidity so as to minimise the growth of pathogens that could adversely affect the fitness for human consumption of the food given the conditions under which the food is to be stored, handled, loaded and transported.
- 25.2 The applicable approved arrangement must validate that the rate of chilling achieves the outcome specified in 25.1.

See also 27.3 and 27.4 which relates to similar requirements for validation of freezing

Although the Government has verified that the chilling and freezing temperatures (See Schedule 5 Clause 24, 26 and 27) will control pathogen build up, you will need to validate that your equipment has the capacity to reduce the product to the acceptable temperatures rapidly and that the time taken to reduce the product temperatures will not allow pathogen populations to grow to the extent that it compromises the fitness for human consumption before reaching the designated temperatures.

## **5. Storage, handling and loading (Part 5)**

The Approved Arrangement must include systems of control for the storage, handling and loading of processed food to protect processed food from contamination and to ensure that the fitness for human consumption is maintained. (Schedule 5, Part 5).

### ***Example:***

Do not store cartons of frozen packed product directly on the floor of a cold store or where condensation can come in direct contact with the carton or its contents.

Ensure 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.

## **6. Transport (Part 6)**

The Approved Arrangement must include systems of control to ensure that processed food is transported under temperature control as specified by the Orders (Schedule 5, Part 6).

That is, what controls are in place to ensure chilled product or frozen product is transported and maintained at these temperatures. System of controls must be in place for the use of official marks, including ensuring the official marks are maintained during transport (Sch 5, clause 22.1)

## **7. Fitness for human consumption (Schedule 5, Part 7)**

The Approved Arrangement must include procedures for evaluating the fitness for human consumption of:

- All processed food received at the establishment

The Approved Arrangement must also include procedures for the identification, segregation and disposal (where applicable) of:

- Processed food not fit for human consumption (including animal food).

Where the Establishment also stores processed food not for export (eg; domestic) procedures must be in place to ensure that processed food not prepared in accordance with the requirements of the Orders is clearly identified, segregated from, cannot contaminate processed food for export or be loaded for export. (Schedule 5, Part 7)

Additionally where processed food is prepared for a particular market (not eligible for export to all markets) the intended market for the food and evidence that the importing country requirements have been met must be readily ascertainable. (Schedule 5, clause 29.1)

## **IX Schedule 8 - Identification, tracing systems, integrity and transfer**

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

Where processed food is transferred as part of an inter-company transfer, the information to be provided on despatch need not be complied with provided the Approved Arrangement documents the controls in place to ensure the product can be identified and traced. (Schedule 8, clause 10.1). Schedule 8, clause 7 provides details as to what information must be provided on despatch.

AQIS has developed a guideline titled “Traceability - A Guideline to Compliance with the *Export Control (Milk & Milk Products) Orders 2005* to help you document procedures in your Approved Arrangement. The guideline is available at [www.aqis.gov.au/dairy](http://www.aqis.gov.au/dairy)

## **X Schedule 9 - Export Documentation**

If applicable the Approved Arrangement must document the measures that will be taken to ensure compliance with Part 5 of the Orders, namely the requirements to:

- Maintain export permits and government certificates under conditions of security.
- Return any revoked export permits, 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)

A Declaration of Compliance must only be made by a person in management and control of operations at the establishment at which the processed food was last prepared and where the Approved Arrangement provides procedures for making Declarations of Compliance and designates the persons who may make such a declaration. (Schedule 9, clause 5.1).

AQIS has developed a guideline to assist you documenting your procedures titled “ Export Documentation – A Guideline to Compliance with the *Export Control (Milk & Milk Products) Orders 2005*. The guideline is available at [www.aqis.gov.au/fish](http://www.aqis.gov.au/fish)

### **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, which comply with the above requirements. 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).

For the issue of export permits where there is no Approved Arrangement see Schedule 9, clause 14 (for exporters who are not occupiers of an Establishment).

## **XI Miscellaneous**

### **Manufacture etc. of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)**

Where an occupier is in possession of an official mark or an official marking device and approval has not been to do so under the *Export Control (Prescribed Goods – General) Order 2005* or by direction from an authorized officer, 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 identify the person(s) who may apply, alter or interfere with official marks and identify 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 86)**

The Orders 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 these Orders as specified in the application.

After reviewing the application, if the Secretary is satisfied that the alternative procedure, standard or other requirement would have an equivalent outcome as the Orders provides for, 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)