



Australian Government

Australian Quarantine and Inspection Service

# **Audit Regime**

## **For Milk and Milk Products**

**AQIS Policy to meet the requirements of the**  
***Export Control (Milk and Milk Products) Orders***  
**2005**

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## **1.0 Background**

The *Export Control (Milk and Milk Products) Orders 2005* (the Milk Orders) together with the *Export Control (Prescribed Goods – General) Orders 2005* (the PGGOs) and the *Export Control Act 1982*, provide conditions and restrictions on the export of milk and milk products.

Under the Milk Orders and the PGGOs, dairy export establishments are required to be export registered and to implement an Approved Arrangement as defined in the Milk Orders. The Approved Arrangement documents how an establishment will comply with legislative export requirements. Audits are conducted to confirm compliance with the Approved Arrangement, as well as legislated and importing country requirements.

The objectives of the Milk Orders are to facilitate trade based on effective procedures to ensure food safety and suitability, compliance with importing country requirements and accurate descriptions of product. Under the Milk Orders, audit provisions are included to substantiate the implementation and adequacy of the Approved Arrangement. On this basis, certification is provided as required by importing countries, thereby facilitating trade.

Unlike previous legislation, the specifics of the audit framework are not detailed in the Milk Orders and this document seeks to provide the parameters for future audits.

## **2.0 Objectives**

The objective of this document is to set the minimum audit framework for the review of the implementation and adequacy of the Approved Arrangements being applied at dairy export registered establishments.

## **3.0 Scope**

The audit regime outlined in this document is applicable to audits of Approved Arrangements conducted by State Regulatory Authorities and AQIS Officers at export registered dairy establishments (both manufacturers and storage establishments).

This document has been prepared as a guide for AQIS staff, authorized officers, approved auditors and dairy export registered establishments.

## **4.0 Introduction**

Audit systems applied to dairy export establishments must at a minimum meet the framework outlined in this document.

State Regulatory Authorities performing the dairy export inspection function on behalf of AQIS must at a minimum audit in compliance with this regime. AQIS will assess State Regulatory Authorities audit systems, to ensure the outcomes of this document are achieved, as a part of the routine verification audits.

The audit regime proposed in this document is intended as a guide. Establishments may request a different audit regime, which must be detailed in the establishments Approved Arrangement and is subject to approval by AQIS.

## **5.0 Definitions used in this document**

<b>the Act</b>	a reference to ‘the Act’ means the <i>Export Control Act 1982</i>
<b>the PGGOs</b>	a reference to ‘PGGOs’ means the <i>Export Control (Prescribed Goods-General) Orders 2005</i>
<b>the Milk Orders</b>	a reference to the ‘Milk Orders’ means the <i>Export Control (Milk and Milk Products) Orders 2005</i>
<b>the Regulations</b>	a reference to ‘the Regulations’ means the <i>Export Control (Orders) Regulations 1982</i>
<b>critical non-compliance</b>	defined by Order 61.3 of the <i>Export Control (Milk and Milk Products) Orders</i>
<b>unsafe</b>	defined by Order 9 of the <i>Export Control (Milk and Milk Products) Orders 2005</i>
<b>unsuitable</b>	defined by Order 10 of the <i>Export Control (Milk and Milk Products) Orders 2005</i>
<b>Tier 1, tier 2 and tier 3</b>	as defined by the “Export Assurance – National Competition Policy Review of the <i>Export Control Act 1982</i> <sup>1</sup> ”.

## **6.0 Scope of Audit**

The objective of an audit is to assess compliance with legislative requirements and the implementation and adequacy of the Approved Arrangement.

The audit regime outlined in this document is only intended to cover food safety issues, including product integrity and traceability, and importing country requirements at the registered establishment. A separate audit regime has been developed to review specific export documentation not under the responsibility or control of the registered establishment.

All audits conducted must be systems based, that is, by assessing the controls in place at the establishment and considering the elements of the Approved Arrangement as a whole in the context of the operations.

Over the period of a year, the audits must assess all elements of the Approved Arrangement and each production process being applied at the registered establishment.

The scope of the audit must include an assessment of all previous outstanding non-compliances.

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<sup>1</sup> See the legislation section of the AQIS website <http://www.aqis.gov.au/legislation>

## **7.0 Classification of Audit Non-Compliances**

A non-compliance is defined as a specific breach of legislated or importing country requirements, or a failure to comply with the establishment's Approved Arrangement.

Non-compliances identified at an audit will be classified as one of the following:

- Critical non compliance – as defined in Table 1 and Order 61.3 of the *Export Control (Milk and Milk Products) Orders 2005*
- Non-compliance – any other failure to comply with legislative, importing country or Approved Arrangement requirements

## **8.0 Reporting Audit Findings**

All non-compliances identified during an audit:

- must be recorded by the auditor in the audit report;
- must be based on the assessment of objective evidence; and
- must include both identification of the area of non-compliance and evidence of that non-compliance.

The non-compliance must be clearly identified with details of the deficiency of the system described in a manner that enables the establishment and all subsequent auditors (from State Regulatory Authority, AQIS and Importing Country Authorities) to fully understand the non-compliance and extent of the non-compliance.

Where a non-compliance is immediately rectified by the occupier, the non-conformance is still to be recorded in the audit report and the corrective action noted.

If a critical non-compliance is determined in accordance with Table 1, then AQIS must be advised as soon as practicable.

Table 1: Non-Compliance categories – Registered Establishments

	<i>Critical Non-compliance</i>	<i>Non-compliance</i>
<b>Definition</b>	<p>A critical non-compliance means a failure or combination of failures to comply with the requirements of the Act, Orders or the approved arrangement:</p> <p><i>Tier 1</i></p> <ul style="list-style-type: none"> <li>• that will result in, or has resulted in, the production of unsafe or unsuitable milk and milk products that is not appropriately actioned in accordance with the requirements of the approved arrangement; or</li> <li>• that prevents an accurate assessment being made as to whether the milk and milk products are fit for human consumption; or</li> <li>• the trade description of the food that does not allow the identity of the food to be established or would jeopardise traceability</li> </ul> <p><i>Tier 2:</i></p> <ul style="list-style-type: none"> <li>• importing country requirements are not met; or</li> <li>• that prevents an accurate assessment being made as to whether the importing country requirements (as per the approved arrangement) have been met.</li> <li>• that prevents an accurate assessment being made as to whether the milk and milk products have an accurate trade description; or</li> </ul> <p>In addition failure to address a corrective action request for a non-compliance within the stated time, or in a manner which is deemed to be ineffective may be a critical non-compliance.</p>	<p>A non-compliance means a failure to comply with:</p> <ul style="list-style-type: none"> <li>• the requirements of the Act, Regulations, Orders, the approved arrangement or a condition of the approved arrangement. ; or</li> <li>• a requirement to complete documentation to demonstrate compliance under the approved arrangement.</li> </ul>
<b>Examples</b>	<p>Where the safety or suitability of the milk and milk products is compromised through:</p> <p><i>Tier 1:</i></p> <ul style="list-style-type: none"> <li>• variation from the approved HACCP plan in relation to Critical Control Points</li> <li>• a critical non-compliance with premises and personal hygiene procedures</li> <li>• evidence of contamination of food, water or equipment</li> <li>• failure to verify the requirements of the approved arrangement have been complied with</li> <li>• milk and milk products that do not comply with FSANZ product standards and is not dealt with appropriately by the registered establishment</li> </ul> <p><i>Tier 2:</i></p> <ul style="list-style-type: none"> <li>• milk and milk products submitted for export that do not comply with product standards for importing countries, such as microbiological standards</li> <li>• non-compliance with trade description requirements that results in a trade description that is false, misleading or deceptive, such as the omission of information or incorrect information.</li> <li>• a failure to address a non-compliance within the stated timeframe, or failure to address the non-compliance in its entirety</li> </ul>	<p>Where the safety or suitability of the milk and milk products is likely to be compromised through:</p> <p><i>Tier 1:</i></p> <ul style="list-style-type: none"> <li>• absence of documentation to demonstrate adequate control of hazards</li> <li>• failure to label chemicals at the establishment</li> <li>• inadequate control of food or ingredients during preparation or processing</li> <li>• variation from the HACCP plan (this may also be a critical non-compliance)</li> <li>• poorly pest-proofed doors and windows</li> <li>• construction of the premises is not sound</li> <li>• premises are not maintained in good repair</li> <li>• inadequate drainage</li> <li>• inadequate lighting</li> <li>• inadequate pressure or water temperature</li> <li>• failure to adequately supervise staff</li> <li>• inadequate stock rotation</li> <li>• variation from the GMP or pre-requisite programs</li> </ul> <p><i>Tier 2:</i></p> <ul style="list-style-type: none"> <li>• Transfer documentation missing some elements</li> <li>• Trade description missing details that do not affect identity and traceability</li> <li>• Details of registration certificate are not current</li> </ul>

## **9.0 Close Out of Non- Compliances**

Non-compliances are to be closed out by an auditor. This can occur at the next scheduled audit if there is minimal risk to food safety or market access. Close out of non-compliance must occur only when objective evidence has been assessed that demonstrates the implementation and effectiveness of the corrective action taken. This may require a further on-site visit, depending on the nature of the corrective action taken. Close out of non-compliances must occur within an appropriate timeframe, commensurate with the risk to food safety and market access.

If an occupier fails to take the required action, then it may constitute a critical non-compliance. The first occurrence of a non-compliance with legislative or importing country requirements, which is not critical, will be recorded in the audit report with rectification dates agreed. In the event that the rectification date for a non-compliance is not met, then the occupier will be asked to show reason why a critical non-compliance should not be allocated. This will result in a renegotiated rectification date if the critical non-compliance is not allocated. In the event that a second rectification date is not met, then a critical non-compliance will be allocated.

If an occupier disputes the non-compliance or the rectification date is disputed, then the occupier must contact the State Regulatory Authority responsible for auditing the establishment or the Dairy Review Unit AQIS and lodge an application for reconsideration of decision in accordance with the provisions of the *Export Control (Milk and Milk Products) Orders*.

### *Critical Non-Compliances:*

Auditors are obliged to immediately notify the nominated Senior Officer in their State Regulatory Authority and the Dairy Review Unit in AQIS.

If an establishment has been allocated a critical non-compliance, the establishment is deemed to present a risk to public health and safety and/or market access, and is unable to continue to process food for export until it can be demonstrated that adequate controls have been implemented.

A follow up audit will be conducted as soon as possible after corrective action has been taken, subject to operational constraints and in consultation with the registered establishment. If no critical non-compliances are found during the follow up audit, the establishment may regain the eligibility to produce product for export.

## **10.0 Sanctions**

In addition to an increase in frequency of audits and additional conditions and restrictions on processing, other sanctions may be applied to establishments, depending on the specific circumstances. These sanctions include, but are not limited to the following:

- Administrative sanctions
- Suspension or revocation of registration
- Withdrawal of AQIS services
- Penal provisions, as provided for in the Act, the PGGOs and the Milk Orders

Additional information on the application of sanctions will be provided in Standard Operating Procedures and Work Instructions issued by AQIS.

The Milk Orders provide for authorised officers to direct action to be taken to ensure compliance with legislative requirements. The occupier of a registered establishment is required under the Milk Orders to comply with directions of an authorised officer.

## **11.0 Frequency of audit**

Minimum audit frequency:

Establishments producing milk and milk products	6 monthly
Establishments only store or handle milk and milk products	12 monthly

Notwithstanding this, there are several reasons for additional visits by an authorized officer or approved auditor:

- To verify corrective actions taken to rectify a non-compliance identified at the last audit
  - It may be necessary for an auditor to follow up on the corrective action to ensure that the Establishment has complied within the timeframe specified. This may occur at a scheduled audit or as a separate visit. The State Regulatory Authority may have an audit regime that determines the audit frequency based on the number of non-compliances found.
- Audit at occupier's request
  - An occupier may request an additional audit, subject to agreement from AQIS and/or the State Regulatory Authority.
- Additional audit at AQIS's request
  - An authorized officer may undertake additional audits in order to verify compliance with the Act, Regulations, Orders or Approved Arrangement. This additional audit may be conducted by AQIS or in consultation with the State Regulatory Authority. These audits will generally occur in relation to an identified risk.
- Unannounced audits
  - The Milk Orders provide for unannounced audits to be undertaken. These may be conducted by AQIS or the State Regulatory Authority.

## **12.0 Transition arrangements**

This audit regime frequency will apply when a new Approved Arrangement is submitted and is approved by AQIS, at which time your existing FPA or AQA ceases to apply. Until that time you will be audited against the defect categories and audit frequencies nominated in the *Export Control (Processed Food) Orders*. A move to an Approved Arrangement will in most cases result in a less frequent audit regime. All dairy export registered establishments must have an approved arrangement in place by 1 July 2007.