

**Approved Arrangement Checklist – EU Requirements**

**Company Name** ----- **Est No** -----

**Location** -----

**Auditor's** -----

**Auditee's** -----

**Audit Date** ----- **Start Time** ----- **Finish Time:** ----- **Breaks** -----

ELEMENT	Compliance	Auditing requirements
<b><i>Raw Milk Supply - Raw Milk Supply (relevant for companies that receive milk directly from farm or part of a milk share arrangement)</i></b>		
<p>1. Raw milk supply in relation to BMCC</p> <p><b><i>Raw milk used in the production milk and milk products must meet requirements for somatic cell counts of less than 400,000 cells per mL, as determined by a rolling geometric average over a period of 3 months, with at least one sample per month</i></b></p>		<p>Company will have a documented system that requires;</p> <ul style="list-style-type: none"> <li>• Raw milk to be included as part of an approved supplier program.</li> <li>• Testing of all raw milk for somatic cells;</li> <li>• That somatic cell count will be based on a rolling geometric average over a three-month period, with at least one sample per month. (procedures to include how this is performed and monitored);</li> <li>• Records of the relevant test results of BMCC in raw milk;</li> <li>• Triggers for corrective action when limits (&gt; 400,000 cells per mL) are exceeded; and</li> <li>• Maintenance of records in regard to noncompliant suppliers and the corrective actions taken, including at what point the milk may be excluded from use.</li> <li>• A link to issuing a declaration of compliance for EU product</li> <li>• If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible"</li> </ul>
<p><i>* Please describe how the specific site has addressed each of the requirements. Evidence (e.g. site procedures) is required to demonstrate how the requirements have been addressed.</i></p>		

<p>2. Raw milk supply in relation to TPC</p> <p><b><i>Milk used in the production of dairy products for export must be manufactured from milk that has a total plate count of less than 100,000 CFU/mL determined by a rolling geometric average over a period of two-month period, with at least two samples per month.</i></b></p>		<p>Company will have a documented system that requires;</p> <ul style="list-style-type: none"> <li>• Testing of raw milk for total plate count;</li> <li>• That total plate count will be based on a rolling geometric average over a two-month period, with at least two samples per month. (procedures to include how this is performed and monitored);</li> <li>• Records of the relevant test results of TPC in raw milk;</li> <li>• Triggers for corrective action when limits (&gt; 100,000 cells per mL) are exceeded; and</li> <li>• Maintenance of records in regard to noncompliant suppliers and the corrective actions taken, including at what point the milk excluded from use.</li> <li>• A link to issuing a declaration of compliance for EU product</li> <li>• If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible"</li> </ul>
<p>3. Raw milk supply in relation to Antibiotics</p> <p><b><i>Note: The EU does not allow for testing to involve heating of samples as this may remove the presence of antibiotic residues.</i></b></p>		<p>Documented procedures as a minimum, will need to include;</p> <ul style="list-style-type: none"> <li>• Testing of raw milk for antibiotic residues (procedures to include how this is performed and monitored);</li> <li>• Maintenance of relevant test results/records for antibiotic testing in raw milk;</li> <li>• Document of triggers for corrective action (limits), including investigation of cause, disposition of milk, requirements for retesting, traceability etc.;</li> <li>• Notification of the relevant authority, including of batch details of any products manufactured from the contaminated milk;</li> <li>• Procedures in place for managing and bringing under control suppliers who consistently fail to ensure that on-farm practices meet requirements for antibiotic residues in raw milk; and</li> <li>• Maintenance of records relating to noncompliant suppliers and the corrective actions taken, including how the milk is excluded from the EU.</li> <li>• A link to issuing a declaration of compliance for EU product</li> <li>• If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible"</li> </ul>

<p>4. Raw milk supply in relation to temperature controls</p> <p><b><i>Milk should to be cooled to 5°C or less within 3.5 hours after the commencement of milking or effectively treated under an alternate cooling regime when manufacturers are able to demonstrate effective management of food safety risks</i></b></p>		<p>The EU requires that milk must be cooled immediately to not more than 8°C, in the case of daily collection, or not more than 6°C if collection is not daily. The EU also requires that during transport the cold chain must be maintained and, on arrival at the establishment, the temperature must not be more than 10°C.</p> <p>Procedures must be documented to include;</p> <ul style="list-style-type: none"> <li>• How companies manage raw milk temperature, including limits for corrective action, frequency of monitoring and process for determining suitability when temperature limits are exceeded</li> <li>• Records of temperature of raw milk collected at farm and received at the establishment</li> <li>• Management of raw milk noncompliant with EU temperature requirements</li> <li>• A link to issuing a declaration of compliance for EU product</li> <li>• If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible</li> <li>• Companies can elect to comply with strict Australian or EU requirements or in line with outcomes of the Milk Cooling Project.</li> </ul>
<p>5. Supply of dairy ingredients (local or imported)</p> <p><b><i>Registered establishments eligible to export milk and milk products to the European Union must ensure that that they have systems in place that demonstrate that the raw milk or other dairy ingredients used to produce milk and milk products for export to the EU meet all the relevant requirements</i></b></p>		<ul style="list-style-type: none"> <li>• Dairy ingredients are supplied under an approved supplier program</li> <li>• A condition of supply is that product must be sourced from an EU registered establishment and there is evidence to support this requirement</li> <li>• Ingredients sourced from overseas must still have evidence of meeting EU requirements</li> <li>• A condition of supply is that the company has evidence that the dairy ingredients supplied meet the EU requirements (BMCC, TPC, Antibiotics, temperatures and product testing).</li> <li>• Evidence of EU eligibility could be in the form of a statement from the supplier or certificates of analysis</li> <li>• As part of the verification program the company should be able to</li> <li>• Supply must be linked to corrective action in the event of non-compliance</li> <li>• Supply must be linked to issuing a declaration of compliance, ie how does the company know it is EU eligible</li> </ul>
<p>6. Product testing requirements for final product</p>		<p>Companies must have a documented program in place that covers the following;</p> <ul style="list-style-type: none"> <li>• Identifies the minimum testing requirements for complying with EU and the FSC requirements, including listeria, salmonella, E.Sakazakii and Staphylococcal Enterotoxins (<i>Where applicable as noted in MICoR</i>)</li> </ul>

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		<ul style="list-style-type: none"> <li>Identifies the limits and triggers for corrective action</li> <li>Identifies how the product will be excluded from the EU, including mandatory notification to the SRA/DAFF</li> <li>Identifies the Australian Standard test method and identifies when the testing must be carried out in a NATA accredited laboratory</li> <li>Provides a link to issuing a declaration of compliance for EU product</li> <li>If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible"</li> </ul>
7. What chemical/physical limits are used to ensure that the <b>water</b> is potable?		<p>Obtain a copy of the annual testing results from the water authority. If there is no town water supply there should be chemical testing as per the Australian Drinking Water Guidelines.</p>
8. Labelling requirements of final product		<ul style="list-style-type: none"> <li>In addition to the standard export labelling requirements companies manufacturing for the EU market must include a best before date on the packaging. Unless the dairy food for export is not for retail sale: See <b>NOTE 1</b> at the end of this checklist.</li> <li>This information should be included in the companies documented system for complying with EU requirements.</li> <li>Provides a link to issuing a declaration of compliance for EU product</li> <li>If company is selling product to a third party and the product is not eligible for export to the EU or will be used as an ingredient for product to the EU then the declaration of compliance and transfer declaration should indicate "not EU eligible"</li> </ul>
9. Requirements in relation to transferring EU eligible product		<p>There is an expectation that the companies dispatch system will identify the following:</p> <ul style="list-style-type: none"> <li>Identifies that a transfer document is required</li> <li>Identifies the format that the transfer document will take and what is the minimum information that it must contain</li> <li>Who has been authorised by the company to sign these documents</li> </ul>

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		<ul style="list-style-type: none"> <li>• A description on what basis the nominated staff can sign these documents</li> <li>• Evidence that nominated staff have received training and or information about the responsibilities associated with signing these documents</li> <li>• Identifies that export product can only be sent to an DAFF dairy registered establishment</li> <li>• Identify how the company know the receiving establishment is registered for dairy</li> <li>• That the transfer document will indicate EU eligibility or otherwise</li> </ul>
<p>10. Requirements for issuing declarations of compliance for EU eligible product?</p>		<p>The system must ensure that for each consignment of milk and milk products exported from the establishment (or provided to a third party for exporter) a declaration of compliance must be issued.</p> <p>The system must ensure that there is evidence to support the issuing of a declaration of compliance, namely;</p> <ul style="list-style-type: none"> <li>• Identifies when a declaration of compliance is required</li> <li>• Identifies the format that the transfer document will take and what is the minimum information that it must contain</li> <li>• Who has been authorised by the company to sign these documents</li> <li>• A description on what basis the nominated staff can sign these documents</li> <li>• Evidence that nominated staff have received training and or information about the responsibilities associated with signing these documents</li> <li>• How staff verify that the EU specific requirements are met (BMCC, TPC, Antibiotics, Temperatures, labelling, sourcing provisions and final product testing);</li> <li>• That the declaration of compliance will indicate EU eligibility (or otherwise)</li> <li>• Identify the circumstances when a dec of compliance cannot be issued</li> </ul>
<p>11. Traceability and eligibility in relation to EU specific shipments</p> <p><i>The auditor will be expected to take sample shipments (provided by DAFF) that have already been sent to</i></p>		<p>It is expected that there is a check of production records, including:</p> <ul style="list-style-type: none"> <li>• A description of the food;</li> <li>• Quantity in the lot;</li> <li>• Unique lot identity;</li> <li>• Date of production;</li> <li>• Full details of all inputs (ingredients)</li> </ul>

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<p><i>the EU and conduct a traceability exercise on one (or more) of the products exported to the EU.</i></p>		<ul style="list-style-type: none"> <li>• Verification of EU eligible ingredients</li> <li>• Trace back to the supplier of ingredients; and</li> <li>• Where farm milk is received at the establishment product must be able to be traced back to the tanker run/s used to produce the batch and verification of (BMCC, TPC, Antibiotics, Temps)</li> <li>• Where re-work product is blended into a batch of product it must be traceable to its original batch and EU eligibility determined.</li> <li>• If the company contract packs or manufactures product</li> </ul>
<p>12. Companies that contract manufacture, where the ingredients and labelling are supplied by a third party.</p>		<ul style="list-style-type: none"> <li>• Companies that contract manufacture and are EU listed need to have documented systems that cover the above elements.</li> <li>• Companies need to have information that supports if a product (including labelling) meets EU requirements.</li> <li>• All information from raw milk through to product testing and sourcing from an EU registered establishment must be included.</li> <li>• If this information is not available (due to commercial in confidence issues) then the manufacturer cannot issue a declaration of compliance and the product would not be eligible for export purposes). The documented system must reflect this and be linked to issuing a declaration of compliance.</li> <li>• Company system should also restrict issuing a transfer document unless EU and export eligibility can be verified (if manufacturer does not have information regarding the source of the ingredients and the accuracy of the labelling then they cannot attest to the goods meeting export requirements, nor can they attest to meeting EU requirements</li> </ul>
<p><b>NOTE 1:</b> REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 - Article 8 Clause 8 Allows variance in the information required to be applied to food where the food is not intended for retail sale e.g. To be further processed, Value added, Used as an ingredient, Used in catering etc..</p>		

**Clause 8.** *Food business operators that supply to other food business operators food not intended for the final consumer or to mass caterers shall ensure that those other food business operators are provided with sufficient information to enable them, where appropriate, to meet their obligations under paragraph 2.*

**Clause 2.** *The food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions.*

The specific legislation can be found at: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R1169>

***All other audit requirements conducted in accordance with the Department of Agriculture and Water Resources Approved Arrangement Checklist for Processing Establishments December 2020***

**Notes and observations:**