DAIRY FOOD SAFETY

FACTORY GUIDELINES

Tasmanian Dairy Industry Authority

13 June 2007

INTRODUCTION

The Tasmanian Dairy Industry Authority (TDIA) is established under the Tasmanian Dairy Industry Act 1994 and administers dairy food safety legislation at federal, state and local government level. The TDIA has the responsibility for ensuring the quality and safety of dairy products and premises in Tasmania and issues and monitors the conditions of dairy licences.

Having all dairy factories operating under an approved food safety program (FSP) registered with the TDIA is the principal method used to carry out this responsibility. More detail is provided in the *Tasmanian Code of Practice for Dairy Food Safety*.

These Guidelines have been prepared by the TDIA, to help new and existing manufacturers achieve compliance with the ***minimum requirements for a dairy food safety system***, and to ensure the necessary product quality outcomes.

You are advised to check on any external requirements that may apply, for example the Food Standards Australia New Zealand, local government legislation and specific importing country requirements. The Tasmanian Department of Health and Human Services may be able to provide additional information.

The TDIA has suitably qualified and experienced staff who are able to assist with advice in preparing your food safety and quality assurance programs.

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RELEVANT ACTS, REGULATIONS AND CODES OF PRACTICE

The main Acts, Regulations and Codes (as amended) that affect the manufacture and processing of dairy produce in Tasmania are listed as follows:-

- *Tasmanian Dairy Industry Act 1994*
- *Tasmanian Code of Practice for Dairy Food Safety*
- *State Food Act 2003*
- *Export Control (Milk and Milk Products) Orders,* published by AQIS
- *Australian Manual for Control of Listeria in the Dairy Industry* (ADASC, 1999)
- *Australian Manual for Control of Salmonella in the Dairy Industry* (ADASC, 1999)
- *Food Standards Australia New Zealand Food Standards Code* (2000)
- *Food Standards Australia New Zealand Food Safety Standards*

USEFUL WEBSITES INCLUDE:

Dairy Industry Act 1994	www.thelaw.tas.gov.au
Department of Primary Industries and Water	www.dpiw.tas.gov.au
Dairy Australia	www.dairyaustralia.com.au
Food Standards Australia New Zealand	www.foodstandards.gov.au
Dept of Health & Human Services	www.dhhs.tas.gov.au/publichealth/foodsafety
AQIS Dairy Review Unit	www.affa.gov.au
Codex Alimentarius Commission	www.fao.org/docrep/W8088E/w8088e00.htm

DEVELOPMENT AND APPLICATION OF HACCP PLANS

All Dairy Food Safety Programs (FSPs) must be based on the Codex document entitled, *"Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application"*. The Codex document is referred to in the following pages in ***bold italics***.

REQUIREMENTS PRIOR TO HACCP

A dairy food safety program is not a stand-alone program but is part of a larger control system which builds on a series of prerequisite programs. Therefore, prior to implementing a dairy food safety program, you need to develop and implement prerequisite programs and supporting systems.

Prerequisite programs provide the basic environment and operating conditions necessary for the production of safe and wholesome food. They should effectively control the common hazards that apply to the whole operation, leaving HACCP to deal with the specific significant product or process hazards.

Prerequisite programs may consider food quality and spoilage, as well as food safety issues.

The exact types of prerequisite programs will vary because their application is product and process specific. Examples of applicable prerequisite programs may include:

1. Adequate document control procedures (HACCP). A statement of management responsibility, system review, including an organisation chart and commitment from the Chief Executive
2. Specifications for all raw materials, including packaging materials
3. End product specifications
4. A Process Flow Chart for each intended process
5. A Hazard Audit Table for each intended process
6. Pest Control procedures
7. Hygiene and sanitation procedures,
8. Document and data approval and use to ensure all records are current, and that completed records are archived under conditions that prevent deterioration
9. Product labelling, identification and traceability
10. Water quality testing programs
11. Equipment – design, installation, calibration and maintenance procedures
12. Personnel training program, including safe food handling and hygiene practices
13. Corrective and preventive action to investigate all incidents of nonconforming product and customer complaints, as well as quality reports and routine test results, to detect and eliminate real or potential causes of problems.
14. Control of nonconforming product, including a product recall procedure.
15. Application of Good Manufacturing Practices (GMP).
16. Product testing program.

MANAGEMENT RESPONSIBILITY

Quality Policy Statement

The company's owner or Chief Executive must document the company's policy about quality and food safety.

This policy statement will describe the company's commitment to continuous improvement of quality and food safety. It will also state the objectives the system will achieve and how customers' expectations will be met. The statement needs to reference compliance with relevant local, state and export regulations.

This policy should be promulgated and must be understood by all staff.

Define scope and purpose of the HACCP Plan:

Scope: The product(s) covered by the plan and the start and end points of the processes addressed.

Purpose: The reasons the plan is being implemented. eg to ensure Food Safety, to enhance Quality, to protect the Environment.

Organisation Structure

The company's organisational structure should be documented in a chart form.

The chart should show the relationship from the Chief Executive Officer to all staff that have a responsibility for quality or food safety.

Position Descriptions

The responsibilities and authorities of staff involved in critical control points (CCP), corrective action or who handle nonconforming product must be documented.

PRE-REQUISITE PROGRAMS

1. CLEANING AND SANITATION

All cleaning and sanitation procedures must be documented and effectively implemented. The areas to be cleaned and sanitised which require a written procedure will include:- all product contact surfaces, processing equipment, especially heat treatment equipment, packaging equipment, conveyors, walls, floors, drains, ceilings, foot baths, dry stores, air conditioning filters, etc. Good housekeeping should be practiced to prevent, or ensure prompt action to remove spillages and waste materials to avoid extraneous matter contamination. Adopt a '*clean-as-you-go'* approach.

Documentation should include:-

a) The frequency of cleaning/sanitation,
b) The type and amount of detergent/sanitiser and the volume of water required,
c) Brand name, & Material Safety Data Sheet,
c) The temperature of the cleaning/sanitising solution,
d) The time taken (if recirculating), the method used and the sequencing of the operation,
e) Methods for safe handling and storage,
f) A schedule for monitoring that cleaning has been effective and the frequency of checking - monitoring effectiveness may include visual inspection and/or environmental swabbing,
g) Corrective actions to be taken where cleaning is found not effective and responsibility for corrective action.

Remember the acronym WATCH – Water, Action, Time, Concentration and Heat

To ensure the correct concentration of cleaning solution is used suitable dedicated measuring equipment must be used to dispense detergents and sanitisers, and checks on the strengths of detergent and sanitiser solutions should be scheduled to ensure an effective clean (refer to manufacturer's instructions).

All detergent and sanitisers must be adequately labelled.

2. PEST CONTROL

You will need to develop, document and effectively implement procedures for the prevention and control of insects, rodents, birds and other pest infestation in and around all storage, production and distribution facilities. This generally involves primary and secondary prevention and control systems. A primary control would be soundly constructed buildings to prevent the entry of pests, and the secondary control comprises extermination and eradication controls (baits, traps, insectocutors).

The procedures shall include a schedule for application of pest control chemicals and equipment, including ;-

- responsibility for monitoring and corrective actions,
- frequency of application and responsibility for application,
- electric insect traps, other traps, use of strip curtains, insect screens and air curtains,
- a schedule for monitoring the effectiveness of the pest control program,
- corrective action procedures where the program is found to be not effective

Where contractors are used, the credentials or evidence of license to apply pest control chemicals and evidence of insurance cover shall be obtained.

Bait maps

To ensure the entire premises are controlled routinely to minimise the risk of pests, a schedule of treatments shall be developed. To aid in the application and verification of pest control, a bait map or location details shall be provided depicting the type of control and the area it is being applied.

Pest control baits and equipment (such as insectocuters) shall not be placed an any areas where food could become contaminated and should be secured to prevent tampering.

A trend report is useful in providing a snapshot of pest activity across the year.

Material Safety Data Sheets (MSDS)

Any pest control chemical used on site must have a material safety data sheet and proof of suitability for use within a food production environment .

3. APPROVED SUPPLIER PROGRAM

An approved supplier program needs to be developed, documented and implemented to ensure that all purchased materials, or services provided, do not introduce any hazards or pose a risk to food safety.

Supplied goods and services will include, but not be limited to:

- ✓ Ingredients, raw materials, cleaning chemicals, packaging, water, etc.
- ✓ Services such as transport, storage, calibration, cleaning contractors, pest control contractors, consultants, contract manufacturers/packers.

The procedure should be documented and implemented and address the following:

- ✓ Methods for approval of suppliers and "emergency suppliers"
- ✓ Methods for removal from the approved program
- ✓ Evidence of the ability to provide desired service/standards, food safety certification, relevant records of up to date certificates and qualifications shall be maintained
- ✓ Where Certificates of Analysis are the means of approval, records of analyses shall be maintained
- ✓ Evidence of compliance to legislation or industry Codes of Practice shall be provided
- ✓ Obtaining raw material or finished product specifications for all purchased inputs
- ✓ A list of approved suppliers and their status must be maintained.

You also need to ensure raw material specifications for all incoming goods and services are documented and maintained.

Temperatures of all potentially hazardous raw materials must be recorded at receival.

Where incoming goods or services are not meeting specification, corrective actions shall be documented and records maintained.

4. FOOD LABELLING AND TRACEABILITY

Compliance with food labelling requirements and an adequate product traceability mechanism is an essential part of a food safety system. Particularly where non-conforming product needs to be retrieved or recalled, and corrective actions put in place. At any stage during the manufacturing process, or when in the possession of an end user, product must be able to be traced back, through the distribution and manufacturing chain, to the raw materials, and finished product traced to the source of dispatch to the final consumer.

As a minimum, all labelling and packaging must comply with the relevant legislation; Refer to the *FSANZ Food Labelling* legislation and AQIS' *Export Control (Milk & Milk Products) Orders.*

Records should link back, via production records, to particular batches of product, and thence to the raw ingredients, packaging and their providers, as well as from product dispatch to the end users.

5. CONTROL OF NON-CONFORMING PRODUCT

It is necessary to have a procedure for the control of any non-conforming goods and services to prevent out of specification products from entering the distribution chain and out of specification raw materials (including packaging) from entering the production process.

The procedures or practices adopted could include some, or all of, the following:-

1) The designation of an area in a cold room or warehouse for the storage of non-conforming stock. To identify this area the perimeter could be marked using a painted line on the floor and/or be distinguished with appropriate signage.
2) Using a separate cold room or storage room to store non-conforming product.
3) Using stickers or signs that identify the status of the product. Signs such as "Hold" etc. should be sufficient, as long as staff are aware of their significance and adequate records kept.

6. WATER QUALITY

Water must be sampled and tested bacteriologically at a minimum of once monthly during periods of operation unless other arrangements have been made with the TDIA. Testing must be carried out by a NATA approved laboratory. If a non conformance is detected, you need to notify the TDIA within 24 hours. The specification is in accordance with the Export Control (Milk & Milk Products) Orders. An annual test of the chemical composition in compliance with the National Drinking Water Guidelines is also required. This information can usually be obtained from your Regional Water Authority if applicable.

Currently, potable water must:

Not contain any *Escherichia coli* in 100mL; and

7. RECALL PROCEDURES

A documented recall procedure is an important part of any food safety and quality system and is a requirement of the TDIA and FSANZ.

A procedure must set out the actions necessary when products meet certain unsatisfactory specifications. It should contain the particular specifications, lay down a contact pathway, outline the actions to be taken and nominate those responsible for initiating the procedural requirements and their delegates.

A recall procedure can be a simple one paragraph statement, or it can be more complex, when specific types of recalls are categorised, depending on the seriousness of the non-conformance.

An up to date list of government and customer contacts must be maintained. FSANZ has developed a Food Industry Recall Protocol, available from their web site, which can be adapted to your operation. This site contains recall procedure and contact details for Recall Action Officers.

8. EQUIPMENT CALIBRATION AND MAINTENANCE

Measuring equipment whose function affects quality and safety must be precise and accurate

When equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

The procedure should address the following:

- A list identifying all inspection, test and measuring equipment including thermometers, scales and balances, temperature recorder/controllers, metal detectors, pH meters, reference weights, etc.
- Identification of calibration equipment and where it is located
- Methods and frequency for calibration and calibration checking
- Acceptable degree of accuracy
- Special conditions for the operations, storage or handling of calibration equipment
- Methods for identifying equipment when its found to be out of calibration
- Methods for identification and review of product produced whilst equipment has been out of calibration

You will need to maintain records of calibrations, calibration checks and any corrective actions taken when equipment is found to be out of calibration, records shall show who is responsible for each activity.

Calibration of scales used to check product weights are required to be calibrated under the Tasmanian Trade Measurement Act 1990 and the Export Control (Milk & Milk Products) Orders.

9. GOOD MANUFACTURING PRACTICE

Procedures and policies need to be developed, documented and implemented, **commensurate with the risk,** relating to personnel, premises, surrounds, equipment, services, and inputs which may impact on the safety and quality of dairy food.

All personnel shall be provided with induction training in reference to the policies and procedures relating to their job description and training records shall be maintained.

Staff Facilities

Adequate facilities (where applicable) shall be made available and be maintained in a clean condition to prevent cross contamination. Consideration shall be given to the following:

- Toilet facilities shall be available within walking distance of all food related activities and not open directly to production facilities
- Adequate locker/storage facilities for personal effects including footwear and clothing.
- Entry to high risk production areas should be via specifically designated changing facilities
- Protective clothing, footwear and head gear should be supplied where applicable
- Adequate eating, drinking and smoking areas should be provided

Personnel hygiene policy

The policy shall identify and develop controls for the following, where applicable:

- Hand washing including appropriate facilities correctly stationed and rules for use of sanitisers
- Rules for eating, drinking and smoking including designated areas for these activities
- Wearing of jewellery, watches and cosmetics

Illness and injury policy

You will need to determine how you handle any employee who is affected by cold, flu or other communicable disease. Where an employee has cuts, abrasion or other open wound, you will need to document a procedure to ensure that the employee does not expose the product to any risk. For rules on diseases for food products refer to the FSANZ Food Safety Standard 3.2.2

Clothing policy

Protective clothing shall be supplied for staff, visitors and contractors wherever applicable. A procedure should be developed where applicable covering the following:

- Rules for clothing, footwear, hairnets, beardnets, protective head gear

- Frequency for changing clothing and methods for cleaning clothing

- Where gloves are worn, a policy shall be developed to ensure the gloves are changed frequently or when contaminated, and in what areas gloves shall be used.

Staff movement policy

Where staff move throughout the site as part of their duties, they may introduce the risk of product contamination from other environments on or around the site. You should identify any potential risks because of staff movements and implement a procedure for its control and maintain records of training in staff movement policies.

Visitor and contractor policy

Where visitors, including contractors, are moving through or around the premises, they may cross-contaminate the product or the environment. Such visitors should be made aware of the company policies in relation to clothing, jewellery, hand washing in and out of the premises and maintain records of entry and departure dates and times.

Premises environment

Policies and procedures shall include consideration in relation to risk to food safety and quality, of the following:

- Processors, manufacturers and distributors site boundaries shall be clearly defined, cleared from potential harbourage of pests, and adequate drainage shall be in place

Where a risk is identified then controls shall be put in place.

Premises construction and layout

Policies and procedures shall include consideration in relation to risk to food safety and quality, of the following:

- High and low risk areas of production should be clearly segregated including coolrooms and other storage areas

- One way flow for manufacture of potentially hazardous foods shall be considered

- Design and construction to minimise accumulation of dirt, debris and pests

- Walls, floors and ceilings shall be impervious and easily cleaned

- On site laboratories should be segregated from production areas

- Covered drainage in wet areas (including footbaths) should be in place, providing adequate outflow

- Lights shall be covered wherever they could shatter and impact on food safety.

Adequate lighting shall be provided for clear working visibility

- Windows and doors linked to storage and production areas shall be fitting and in good condition to control dust, vermin, and airborne organisms

- Air should be filtered where necessary and pressure differentials in place between high and low risk production areas for potentially hazardous foods
- All areas for storage of ingredients, packaging; and cleaning, manufacturing and agricultural chemicals; and any flammable materials shall be secured, properly enclosed and adequately ventilated
- All incoming service lines such as gas, electricity, hot and cold water shall be adequately protected and clearly marked

Equipment
All equipment used to prepare, process, pack and cool product shall:

- Be designed to be easily cleaned
- Be sited to allow ease of cleaning
- Be frequently assessed to ensure it is in good condition
- Not pose a potential risk to food safety

Preventive Maintenance

Policies and procedures shall include the following:

- Planned maintenance program for all food process equipment, premises, surrounds
- Contactors and in-house maintenance teams shall adhere to company hygiene, clothing and staff movement policies.

Cross contamination

Procedures for prevention of cross contamination shall be developed, including:

- Contamination from extraneous packaging
- Separation of raw materials and finished products
- Separation of utensils used for preparing raw materials and finished product
- Allergens should be identified and controlled to prevent cross contamination
- Use and management of transport vehicles

Retention Samples
A procedure shall be implemented to ensure that product samples are retained for an appropriate period for investigation of potential issues pertaining to safety, quality or regulatory compliance. The retention time shall be determined based on the product shelf life.

Wood & Glass Policies
Procedures for the exclusion/control of timber and glass in production areas shall be developed and effectively implemented.

Services
Compressed air and steam must be managed to ensure they cannot pose a food safety risk if they come into direct contact with the product, for example direct steam injection or air agitation of silos.

CODEX HACCP REQUIREMENTS

ASSEMBLE HACCP TEAM – STEP 1.

"The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP Plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on-site, expert advice should be obtained from other sources."

The HACCP team should have sufficient expertise to be able to:

- Identify potential hazards;
- Assign levels of severity and risk (likelihood of occurrence);
- Identify critical control points, recommend control measures, critical limits and procedures for monitoring;
- Recommend appropriate corrective actions when deviations occur;
- Recommend or conduct investigations and/or research related to the HACCP plan (if information is not available).

SCOPE

"The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes?)."

The HACCP team needs to define and document the scope (boundaries) of the HACCP plan. The scope should include the starting and finishing point, the general classes of hazards to be addressed and whether it is food safety only, or are quality aspects included.

The HACCP scope must be clearly defined and cover the following:

- start and end point of the HACCP Plan;
- all produce or product, which fall within the scope. Note that businesses with multiple products may find it effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP Plan;
- specific activities that are not covered in the prerequisite programs or other HACCP Plans e.g. rework, etc.
- classes of hazards addressed by the HACCP Plan.

DESCRIBE PRODUCT – STEP 2.

"A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including Aw, pH, etc.), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution."

Some product characteristics are important as they impact on the inherent safety of the product and therefore should be included in the product description. This ensures that the product characteristics are considered when identifying hazards, conducting the hazard analysis and determining the control measures.

Product descriptions should focus on food safety issues, but other non food safety parameters may be included (refer to attachment No. 1).

IDENTIFY INTENDED USE AND INTENDED CONSUMER – STEP 3.

"The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered."

The intended use and the intended consumer(s) of the product must be identified, as this impacts on the hazard identification and hazard analysis steps. For example, products manufactured specifically for consumption by susceptible consumer groups may require tighter controls e.g. infants and immuno-compromised individuals.

The description of the intended use should identify, where appropriate:

- normal usage conditions, e.g. storage temperatures, and how it is likely to be eaten;
- potential for abuse of the product, e.g. the likelihood on incorrect storage or handling of the product, resulting in unacceptable growth of micro-organisms.

CONSTRUCT A FLOW DIAGRAM – STEP 4

"The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation."

A flow diagram may take different forms, however the diagram should have sufficient detail to allow a clear understanding of the process inputs and outputs in order to be able to effectively identify hazards.

The inputs must be described. These include raw materials, ingredients, food additives, and wrapping and packaging materials or containers that come into direct contact with or form part of the product e.g. plastic bag liners etc.

Edible outputs should also be shown. Each of these may initiate a separate process flow diagram of its own and form part of another HACCP Plan with a different end product.

The flow diagram should include all activities which impact on the process which has been scoped e.g. reworking etc (refer to attachment No. 2).

ON-SITE VERIFICATION OF FLOW DIAGRAM – STEP 5

"The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate."

It is important that the process flow diagram reflects what is actually happening with the process. On completion, you should confirm the flow diagram by:

- walking through the process to determine whether there are any additional risks presented to the process from the surrounding environment;
- discussing the process flow diagram with processing staff to ensure it accurately describes the process steps and all inputs and outputs.

HAZARD IDENTIFICATION, HAZARD ANALYSIS AND CONTROL MEASURES

"List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (PRINCIPLE 1)."

A thorough hazard analysis is essential in preparing an effective HACCP Plan. Where the hazard analysis is not performed correctly, hazards requiring control may not be identified and the plan is unlikely to be effective, no matter how well it is implemented.

The objectives of the hazard analysis and the identification of control measures for each hazard are:

- to identify all hazards reasonably expected to occur and their associated control measures at each process step;
- to identify any required modifications to a product or process to provide a greater food safety assurance;
- to provide a basis for determining the process critical control points (See Principle 2).

LIST ALL POTENTIAL HAZARDS

"The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption." All biological, chemical and physical hazards should be considered.

The hazard identification is effectively a brainstorm by the HACCP team of the hazards that may be reasonably expected to occur at each step in the process**.** This includes an assessment of the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and the consumers of the product. Based on this review, a list of potential biological, chemical and physical hazards that may be introduced, increased or controlled at each step in the production process should be developed.

CONDUCT A HAZARD ANALYSIS (Principle No.1)

"The HACCP team should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be included:

- ***the likely occurrence of hazards and severity of their adverse health effects[1];***
- ***the qualitative and/or quantitative evaluation of the presence of hazards;***
- ***survival or multiplication of microorganisms of concern;***
- ***production or persistence in foods of toxins, chemicals or physical agents; and***
- ***conditions leading to the above."***

During this stage, the HACCP team decides which of the hazards identified as being reasonably expected to occur must be addressed in the Hazard Identification and Analysis/HACCP Plan. To do this, each hazard must be analysed to determine its significance in relation to the designated product outcome.

While rating systems may be used to estimate the significance, they are optional and other methods such as assigning significance based on experience are acceptable. If a rating system is used, it must be transparent and relate to the product outcome. For the purposes of conducting a hazard analysis, consideration of control measures is not important at this stage.

CONTROL MEASURES

"The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure."

For each hazard identified as being reasonably expected to occur, list the control measures that are in place. Control measures may be specific to the process step where the hazard has been identified or, alternatively, control may be via a more general prerequisite program. The term control measure is used because not all hazards can be prevented, but virtually all can be controlled.

Each control measure must be identified, implemented and working on a consistent basis to effectively control the specified hazards. Where control is not effective, the HACCP team should determine the gaps and implement the controls as necessary.

DETERMINE CRITICAL CONTROL POINTS (See Principle No. 2)

"There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree, which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure."

Once significant hazards and the control measures have been identified for each step in the process, it is necessary to determine whether that step in the process is a critical control point (CCP). A CCP is a point, step or procedure at which control is applied to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

The information gathered during the hazard analysis is essential in identifying which steps in the process are CCPs. One method which may be used to facilitate the identification of a CCP is the use of the *CCP decision tree* (attachment No.3). Although the application of the CCP decision tree may be useful in determining whether a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. Other methods of CCP identification can be used e.g. expert knowledge. Whatever method is used, there should be two clear considerations for a CCP determination:

- whether the hazard is at an unacceptable level in relation to the expected product outcome; and
- whether the control measure(s) is available to eliminate, or reduce the hazard(s) to an acceptable level (product outcome).

The existence or non-existence of a CCP should never be assumed without working through some systematic decision making process. Where there is more than one CCP controlling a hazard, each one will contribute to achieving the product outcome. The acceptable level of food safety achieved at each CCP may not achieve the product outcome individually, but the combined effect of the CCPs will.

ESTABLISH CRITICAL LIMITS FOR EACH CCP (SEE PRINCIPLE 3)

"Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w, available chlorine, and sensory parameters such as visual appearance and texture."

Critical limits relate to process parameters that separate acceptable from unacceptable observations or measurements. For example: *Pasteurisation - Critical Limits - >72°C/>15secs.*

When the critical limits for a critical control point have been met, (when 72°C/15 seconds has been achieved) the process and/or product is deemed to meet the product outcomes, i.e. it is "safe" at that point in the process. Consequently, where critical limits are exceeded, or not achieved, then the process or product may be considered "unsafe".

Once the critical limits have been determined they should be validated. This involves the scientific activity/data that demonstrates that the specific hazard(s) at the CCP is eliminated or reduced to an acceptable level i.e. is compliant with product outcomes for example phosphatase <10µg/mL of p-nitrophenol indicates adequate pasteurisation conditions have been met.

More restrictive limits than those set for CCPs are commonly used to provide early warning of an impending CCP violation. These are referred to as Operating Limits, Acceptable Range, or Tolerances and allow early action to be taken by the manufacturer to avoid the production of unsafe product. They should not be confused with critical limits.

ESTABLISH A MONITORING SYSTEM FOR EACH CCP (SEE PRINCIPLE 4)

"Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company."

The monitoring of a critical control point relative to its limits must be able to identify when critical limits have been exceeded. This can be done on either a continuous or batch basis and will largely depend on the particular process and/or CCP. It should be remembered however, that the higher the frequency of the monitoring, the smaller amount of unsafe product that will be produced should a CCP limit be exceeded.

Monitoring procedures should provide information on:

- **who** will undertake the monitoring (this person must be trained and have appropriate responsibility to initiate corrective action or a computer with appropriate recording and software controls);

- **what** will be monitored;
- **where** monitoring will occur; and
- **how** critical limits will be monitored.
- **when,** frequency of the monitoring;

To ensure monitoring is effective and compliant, the following points should be implemented:

- Monitoring procedures should provide real time measurements or short-term feedback and should not rely on lengthy test methods for results e.g. microbiological assessments requiring extended incubation times are not practical if the product has to be held pending a result at the CCP.
- Monitoring equipment e.g. thermometers, clocks, scales, pH meters, water activity meters etc. should be properly selected to record data within an appropriate range and be calibrated to a recognised standard.
- Monitoring records must be kept and all monitoring activities recorded. A senior person within the organisation e.g. supervisor should review and sign the records daily.

ESTABLISH CORRECTIVE ACTIONS (SEE PRINCIPLE 5)

"Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping."

Where the critical limits for a CCP have been exceeded, the following corrective actions must be taken:

- Bring the defective process back under control.
- Determine and control any affected product. All product processed back to the point where the CCP was known to be within limits must be considered "affected" and be treated in accordance with a procedure for "Non-conforming Dairy Produce"
- Take action to ensure the non-conformance does not recur. In this regard the investigation should determine the root cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure the corrective action is effective. This step may involve reassessment of the control measures and/or modification of the HACCP Plan.

Corrective actions may be designed so that they are implemented when the monitoring results indicate a trend towards loss of control of a CCP. This will bring the process back into control before the deviation leads to a product outcome not being met and a potential threat to public health.

Corrective action responsibilities should be defined in the HACCP Plan, and recorded.

ESTABLISH VERIFICATION PROCEDURES (SEE PRINCIPLE 6)

"Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- ***Review of the HACCP system and its records;***

- ***Review of deviations and product dispositions;***
- ***Confirmation that CCPs are kept under control.***

Where possible, validation activities should include actions which confirm the efficacy of all elements of the HACCP plan."

Verification activities are documented standard tests, methods and procedures, which, in addition to the monitoring activities, provide an assurance that the HACCP Plan is working correctly and according to documented procedures.

For example, pasteuriser time/temperature monitoring versus daily divert checks. Each HACCP Plan should include verification procedures for individual CCPs and the overall HACCP Plan.

The verification procedures (both internal and external) should detail who is to undertake the verification process(es), the frequency of verification (including sampling regimes), what is to be verified and how verification is undertaken.

Verification requirements may vary with each process but commonly include the following activities.

HACCP PLAN VALIDATION

The HACCP Plan is validated at least when it is first developed and following revision, by a competent, internal or external validator on behalf of the company/operator.

Validation involves obtaining evidence that **all** steps of the HACCP Plan are effective in achieving the product outcomes. HACCP Plan validation includes:

- review of the scope, product description, intended use;
- review of the process flow and verification;
- review of the hazard identification and analysis;
- confirmation the control measure(s) and critical control points eliminate or reduce the hazard(s) to an acceptable level (product outcomes);
- review of CCP determination;
- review of justification of critical limits, including validation information (HACCP Plan only);
- determination of the ability for equipment to deliver the parameters of the critical limit, which may include accurate temperature and flow rate checks);
- determination of whether monitoring activities, corrective action, record keeping and verification activities are appropriate and adequate for the defined hazard and relative to product outcomes.

HACCP SYSTEM AUDITS (INTERNAL ONLY)

HACCP system audits should review the actual practices and application of any procedures written in the HACCP Plan. HACCP system audits may include on-site observations to cover e.g.:

- introduction of a new raw material;
- changes to the formulation, processing or packing methods and/or system;
- a change to the intended product use;
- ensuring product description and process flow diagrams continue to be accurate;
- monitoring required by the HACCP Plan at the CCPs is performed;
- ensuring processes are operating within established critical limits;
- where monitoring has indicated a deviation from critical limits, affected product has been controlled, as documented in your PSP, and corrective actions have been followed;
- seeing that records are filled out accurately.

The audits may cover the entire HACCP Plans or selected parts. A full review is recommended periodically to ensure that the HACCP Plans continues to meet expected outcomes and remains suitable. Where possible, reviews should be carried out under a formal audit procedure with appropriate follow up for non-conformances to the HACCP Plans.

Additionally, a review of the HACCP system should occur when changes that may impact on the HACCP Plans occur. Examples of changes include:

- introduction of a new raw material;
- changes to the formulation, processing or packing methods and/or system;
- a change to the intended product use;
- a significant food safety event, e.g. pathogen or foreign matter contamination.

In addition, a review of the HACCP Plan may be undertaken following customer complaints.

PRODUCT SAMPLING AND TESTING

Testing of final product and process capability is required to verify that outcomes of the HACCP Plan have been met and product meets customer expectations, specifications and regulatory standards.

The testing requirements would be set out in the HACCP program**. Test records must be maintained and should clearly indicate whether a product has failed or passed the test and what corrective action was taken when the product failed the test.**

Refer to the ‘Minimum Testing Guidelines for Dairy Products’ on page 24.

- Samples should be representative of the finished product being sampled and must remain representative. The portion of the sample that is tested, e.g. a sub-sample taken in the laboratory, should also be representative of the product.

- All finished product testing should be undertaken in a laboratory accredited or recognised in the appropriate category for the required test

DOCUMENTATION AND RECORD KEEPING (SEE PRINCIPLE 7)

"Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation."

Quality system manuals are living documents and need to be regularly reviewed to keep pace with the changes that occur. Ensure that:

1) The document is the current issue.
2) The document is complete.
3) Changes to the document have been made by an appropriate staff member.

All quality documents should be identified, easily, retreivable and stored in a secure, suitable area.

TRAINING

"Training of personnel in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

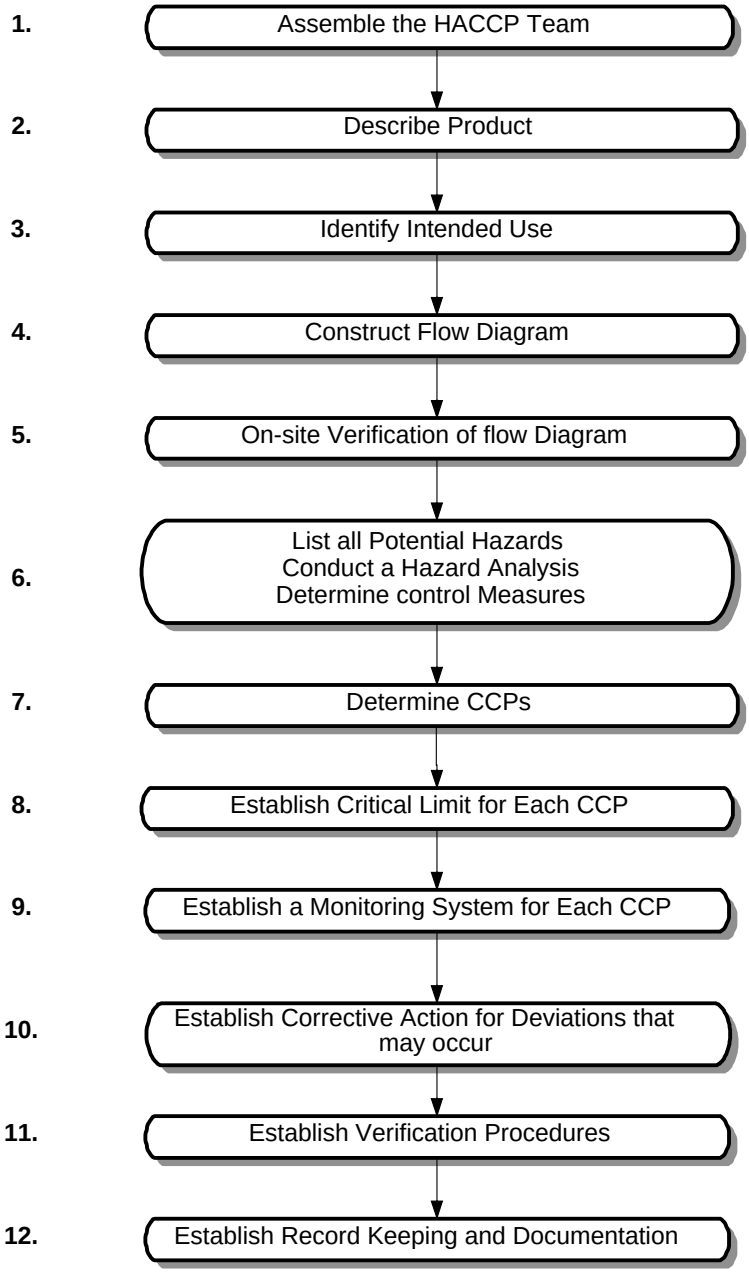
Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP."

There must be a program for training all staff, who will have food safety and quality related responsibilities and for keeping all staff up to date in terms of hygienic handling of food and personal hygiene. Some staff with particular duties may require specific qualifications and special training.

Training records need to be maintained and, ideally, one person should be responsible for the training program. It is beneficial for ALL staff to understand the basic principles of food safety .

For the HACCP Plan to be successful, it should be effectively implemented. The first stage of effective implementation is to ensure that effective training has been undertaken.

LOGIC SEQUENCE FOR APPLICATION OF HACCP



See Diagram 2

PRODUCT DESCRIPTION – EXAMPLE ONLY

Surface Ripened Cheese are made from warm pasteurised milk to which non-animal rennet and lactic acid culture has been added. Curd is drained, brine salted and ripened on shelves.

Penicillium camemberti mould is sprayed over the Brie and Camembert curd wheels. This cheese has an even white surface; its interior is a lively yellowish colour, with a white centre core. Proteolyttic breakdown in mature cheese results in ammonia-like flavours.

Limburger, Limemberg and Romadur curd is smeared with *Brevibacterium linens*. This, combined with *P. camemberti* produces a brownish-red surface growth visible beneath the white mould. *B. linens* breaks down cheese protein to amino flavours and a pungent odour by degrees.

PRODUCT SPECIFICATION

PRODUCTS	Surface Ripened Cheese: Brie, Camembert, Limemberg, Limburger and Romabur
Customer	General public through selected supermarkets and outlets
Composition	Milk, salt, lactic acid cultures, non-animal rennet. *Penicilium camemberti* is used in Camembert and Brie; *Brevibacerium linens* in Limburger, Romadur and Limemberg.
Condition before consumption	Refrigerated, or brought to room temperature; ready to eat
Method of preservation	Pasteurisation, followed by refrigeration at less than 5ºC
Packaging - Primary, secondary	Laminated, breathable barrier film, cardboard shipper carton.
Condition at distribution	Chilled to less than 5ºC
Method of distribution	Insulated and refrigerated transport
Shelf life	6 weeks
Label instructions	Serve or at room temperature
Distribution instructions	Keep at less than 5ºC
Chemical composition	As per FSANZ *Food Standards Code* and Schedule 6 of AQIS' *Export Control (Milk & Milk Products) Orders*
Microbiological composition	As per FSANZ *Food Standards Code* and Schedule 6 of AQIS' *Export Control (Milk & Milk Products) Orders*

INTENDED USE

Condition before consumption	Serve or at room temperature
Method of use by customers	Eat direct or use with complementary foods and crackers
Type of customer	General public
High-risk consumers?	Those sensitive to allergens present in dairy products

Minimum Sampling Guidelines for Dairy Products

These Sampling Guidelines apply to all dairy manufacturers, producing for the domestic market and in some cases the export markets (see Export Control (Milk & Milk Products) Orders).

The guidelines are structured to verify the microbial efficacy of your HACCP system and provide a compliance/non-compliance decision with stipulated end-point food standards. The standards listed are domestic (Food Standards Australia New Zealand Food Standards Code) and export (Export Control (Milk & Milk Products) Orders).

For exporters, tests against specific requirements of importing countries may have to be carried out.

These guidelines will:

- define minimum sampling for microbiological attributes that will verify the effectiveness of an establishments HACCP system;
- provide regulatory bodies with confidence that standards are being met;
- provide consistency and uniformity across dairy product sampling and testing;
- Assist designers of HACCP systems to include minimum sampling in the HACCP plan, and so create consistency in determination of appropriate minimum testing for HACCP system verification.

Sub-samples from the same product line can be composited for testing. If the results of a composited sample exceed the microbiological limit, all products from the composited sample would be subject to clearance testing.

For some products, chemical testing will be essential for determining food safety and these tests must also be included in the testing required in the HACCP program. **The test would include pH for yoghurt and phosphatase for milk and cream.**

> **Note**: The guidelines should be seen as the minimum sampling and testing that will be required and would only apply to small production runs (less than 1000Litres/day). For larger factories testing requirements would be determined in consultation with the TDIA.

Testing must be carried out in a TDIA-approved laboratory.

Clearance testing for product found to exceed microbiological or chemical limits

When a product fails the standards the product line that failed to meet the standard must be sampled and tested until five consecutive batches meets the standards. The product should be tested against all the specifications over the page, even if only one microbiological specification was exceeded.

If a dairy product fails the Listeria test, the clearance procedures per the Listeria Manual apply.If product fails the Salmonella test the clearance procedure per the Salmonella Manual apply.

MINIMUM TESTING GUIDELINES FOR DAIRY PRODUCTS

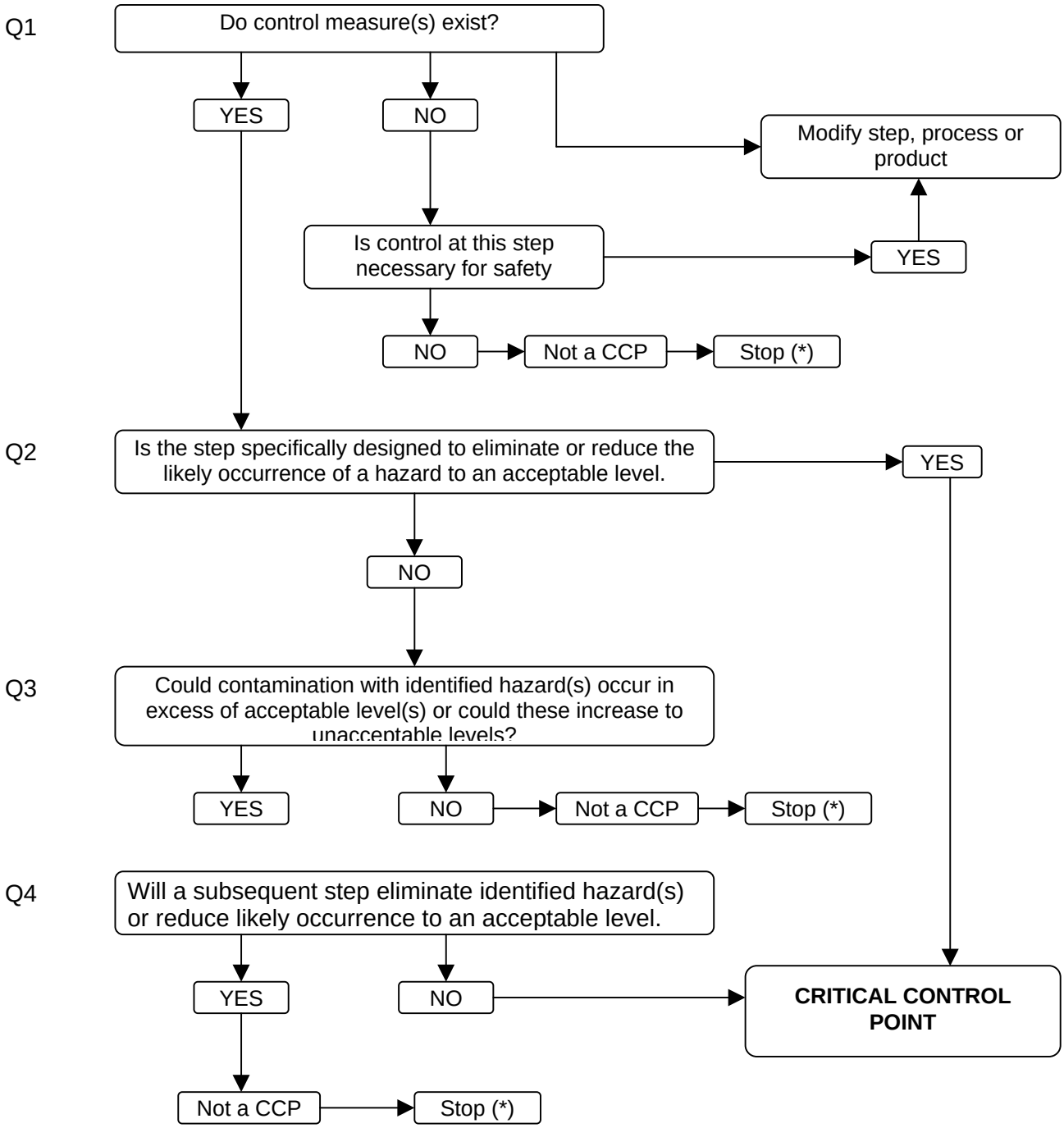
Product Line	Risk Level	Test	Standard
Pasteurised Liquid Milk	High	Phosphatatse Coliforms E. coli. L.monocytogenes	< 10 µg/mL < 100/mL < 1cfu/mL Not detected in 25g
UHT	Low	Sterility	Aust Standard
All Cheese	High	L.monocytogenes Coliforms CPS E.coli	Not detected in 25g < 100/g < 1000cfu/g < 10cfu/g
Raw Milk Cheese Moisture < 36% (Other conditions apply)	High	Campylobacter CPS Coliforms Escherichia coli L monocytogenes Salmonella	Not detected/25g <1000/g <100/g <10/g Not detected/25g Not detected/25g
Dried Milk Powder	High	Salmonella	Not detected in 25g
Butter	Low	E.coli	Not exceeding 10cfu/g
Farmhouse Butter	High	Campylobacter CPS Coliforms Escherichia coli L monocytogenes Salmonella SPC/g	Not detected/25g <100/g <100/g <10/g Not detected/25g Not detected/25g <50,000 cfu/mL
Dairy Desserts/Yoghurt (pH<4.5)	High	Coliforms E.coli CPS L.monocytogenes	<100/g < 10cfu/g < 100cfu/g Not detected in 25g
Sweetened Condensed Milk	Low	No requirements – not a food safety issue	
Cream	Low	E.coli L.monocytogenes	Not exceeding 10cfu/g Not detected in 25g

NOTE:

- **Testing frequency is a minimum of fortnightly for each product line.**
- New licensees may be required to demonstrate safe food credentials (process validation) by providing results at more intense testing frequency for a period to be determined by the TDIA and incorporated in their HACCP program.
- Additional testing requirements may apply in the case of products intended for export, according to the importing country requirements.

EXAMPLE OF DECISION TREE TO IDENTIFY CCPS

(ANSWER QUESTIONS IN SEQUENCE)



* Proceed to the next identification hazard in the process

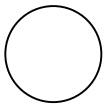
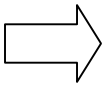
EXAMPLE OF A PROCESS FLOW CHART (PFC)

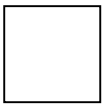
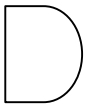
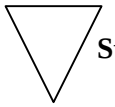
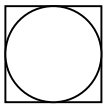
Name of Company: A Milk Company **Document:** Process Flow Chart

Product: Pasteurised & Homogenised Milk - 600 ml & 1 litre Cartons

Date issued: 1/10/03 **Managers Signature:..... Revision Number:** 1 **Page 1 of 1.**

Step Number	Process Symbol	Operation
1.		On farm milk collection
2.		Transport of milk
3.		Receival of milk at factory
4.		Raw milk storage
5.		Pasteurisation
6.		Pasteurised milk storage
7.		Packaging
8.		Storage/Dispatch

Symbols for Flow Diagrams:  **Operation;**  **Transportation;**

 **Inspection;**  **Delay;**  **Storage;**  **Combined Activity.**

EXAMPLE HAZARD ANALYSIS USING A MATRIX

Step	Input	Hazard	Significance			Control Measure
			Severity	Risk	Significance	
1. On farm milk collection	Milk in farm vat collected by tanker driver	M – growth of bacteria	4	B	14	Milk temperature checked at pick up. Thermometer calibrated.
		Q – taint/odour	4	B	14	Graded at pick up and not collected if milk has taint or off flavour
		C – antibiotics	3	B	9	Milk visually checked for signs of antibiotics in milk.
		C – pesticides	3	B	9	Product tested monthly to verify milk free from pesticides
		P – foreign matter	5	B	19	Milk visually checked at pick up for foreign matter. Filtered before pasteurisation
2. Transportation of milk	Milk transported in tanker	M – growth of bacteria	5	D	24	See next step
3. Receipt of milk at factory	Milk in tanker	M – growth of bacteria	4	B	14	Temperature maintained at ≤6ºC and grade of milk checked when received at factory. Thermometer calibrated.
		Q – taint/odour	4	B	14	Graded at factory.
		C – antibiotics	3	B	9	Milk in each tanker tested for antibiotics
4. Raw Milk Storage	Milk from tankers into silo for storage	M – growth of bacteria	4	B	14	Silo temperature monitored regularly Thermometer calibrated.
		C – antibiotics	3	B	9	Milk in each silo tested for antibiotics
		Q – composition incorrect	4	B	14	Composition measured.
5. Pasteurisation and cooling	Heating and cooling of milk in pasteuriser	M – Survival of pathogens & cross contamination	1	B	2	Milk pasteurised at □72ºC for □15 seconds. Temperature/time monitored and recorded continuously. Chart checked daily against in line thermometer. Chart and thermometers verified 6 monthly. Validation of pasteuriser as per TDIA validation requirements
		C – brine	4	B	14	Pressure differential.
6. Pasteurised milk storage	Milk silo storage	M – growth of bacteria & x contamination	2	B	5	Silo temperature maintained ≤4ºC. Thermometer calibrated. Cleaning procedure
7. Packaging	Packaging	M – growth of bacteria & x contamination	2	B	5	Package seal check.
		Q – no traceability	3	C	13	Apply U/B date and correct label to each package and check.
		Q – volume incorrect	4	B	14	Volume checked by weighing packages. Scales checked and calibrated.
8. Storage & Dispatch	Coldroom storage	M – growth of bacteria	2	B	5	Keep refrigerated at ≤4ºC delivered. Thermometer calibrated.

ASSESSMENT OF SIGNIFICANCE FOR FOOD SAFETY USING A MATRIX

Based on the WRAC system for risk management (Reference: Advancing Food Safety, Volume 2, No. 7 Page 33-34), the matrix below allows a more consistent approach to determine the significance or otherwise, of any identified food safety hazard (chemical, biological or physical). This then allows the identification of CCP status control measures at a glance ie. For those control measures developed to eliminate, prevent or reduce significant hazards for an acceptable level at least one must be a CCP (even though it may occur at a later step in the process).

Severity (Consequence)

1. Can cause fatality
2. Can lead to serious illness
3. Can cause a product recall
4. Can generate a customer complaint
5. Not a significance

Risk (Likelihood)

A. Common occurrence
B. Known to occur or "it happened at our premises"
C. Could occur or "I've heard of it happening" (published information)
D. Not likely to occur
E. Practically impossible

Severity	**Risk**				
	A	**B**	**C**	**D**	**E**
1	**1**	**2**	**4**	**7**	11
2	**3**	**5**	**8**	12	16
3	**6**	**9**	13	17	20
4	**10**	14	18	21	23
5	15	19	22	24	25

A value of 1-10 indicates a significant hazard (ie above the line and shaded), which signifies that control measure(s) must be put in place. Hazards that are not significant will have values of 11-25. It is up to the HACCP team to determine whether it makes good sense to have any control measures in place (ie CP status control measures) to further reduce the risk of the hazard.

By recording the values in the Hazard Analysis worksheets, others (including food safety auditors) can then better understand the logic applied by the original HACCP team.

HAZARD AUDIT TABLE (HAT) - EXAMPLE ONLY

Step	Hazard	Control Measure	CCP	Critical Limit	Monitoring	Corrective Action	Records
1. On farm milk collection	Growth of bacteria	Milk temperature checked at pick up.	CP	≤4ºC	What: raw milk How: thermometer Where: farm When: before pick-up Who: tanker driver	Reject: ≥7ºC Accept: ≤4ºC if 5-6ºC & grade OK Advise:Supplier	Docket
	Taint/odour	Graded at pick up and not collected if milk has taint or off flavour. As per grading manual.	QCP	Taint / strong odour	What: raw milk How: taste & smell Where: farm When: before pick-up Who: tanker driver	Reject: unacceptable grade Accept:: 1st & 2nd grade Advise:Supplier	Docket
	Antibiotics	Milk visually checked for signs of antibiotics in milk. As per grading manual.	CP	Milk blue	What: raw milk How: visual Where: farm When: before pick-up Who: tanker driver	Reject: unacceptable grade Accept:: 1st & 2nd grade Advise:Supplier	Docket
	Foreign matter	Milk visually checked at pick up for foreign matter. As per grading manual.	CP	Milk has foreign matter	What: raw milk How: visual Where: farm When: before pick-up Who: tanker driver	Reject: unacceptable grade Accept:: 1st & 2nd grade Advise:Supplier	Docket
3. Receipt of milk at factory	Growth of bacteria	Temperature maintained and grade of milk checked when received at factory.	CP	≤4ºC	What: raw milk How: visual Where: Milk receival When: before unload Who: factory milk receiver	Reject: >10ºC Accept::≤4ºC Retain: 4-10ºC and chill to 4ºC immediately.	Receival book
	Taint/odour	Graded at factory.	QCP	Taint / strong odour	What: raw milk How: visual Where: Milk receival When: before unload Who: factory milk receiver		Receival book
	Antibiotics	Milk in each tanker tested for antibiotics	CP	ND	What: raw milk How: Snap test Where: milk receival When: before unload Who: factory milk receiver		Receival book

Step	Hazard	Control Measure	CCP	Critical Limit	Monitoring	Corrective Action	Records
4. Raw Milk Storage	Growth of bacteria	Silo temperature monitored regularly	CP	≤4ºC	What: Raw milk How: Thermometer Where: Silo When: before use Who: Operator		Silo book
	Antibiotics	Milk in each silo tested for antibiotics	CCP1	≤0.003µg/ml	What: Raw milk How: Delvo Where: raw milk silo When: before use Who: Lab tech.	Reject: milk >0.003 g/ml & dispose of milk Advise: Manager	Lab record book
	Composition incorrect	Composition measured.	QCCP	Fat – 32g/kg Protein – 3.1 Freezing point	What: Raw milk How: Scan Where: Raw milk silo When: before use Who: Lab tech.	Reject: <32 fg/kg fat, 31g/kg protein Advise: Manager	Silo book
5. Pasteurisation and cooling	Survival of pathogens & cross contamination	Pasteurisation. Temperature/time maintained.	CCP2	≥72ºC for□15 sec. Cool to ≤4ºC	What: Product How: Chart Recorder Where: Pasteuriser When: continuously Who: operator	Reject: product <72ºC for 15 sec. Product diverted to balace tank.	Chart recorder
6. Pasteurised milk storage	Growth of bacteria & cross-contamination	Silo temperature maintained.	CCP3	≤4ºC	What: Pasteurised milk How: thermometer Where: finished product silo When: continuously Who: operator	Reject: >4ºC & poor grade. Retain: >4ºC if grade if chill to ≤4ºC immediately. Advise: Manager	Chart recorder
7. Packaging	Growth of bacteria & cross-contamination	Package seal check.	CCP4	Packages sealed	What: packaging How: dye test Where: carton line When: half hourly Who: operator	Reject: all failed packages to point back to where packages are OK.	Log sheet No.1
	No traceability	Apply U/B date and correct label to each package and check.	QCP	FSANZ & AQIS requirements. All products traceable	What: product packaging How: u/b dates Where: carton line When: half hourly Who: operator	Reject: all failed packages to point back to where packages are OK.	Log sheet No.1

Step	Hazard	Control Measure	CCP	Critical Limit	Monitoring	Corrective Action	Records
	Volume incorrect	Volume checked by weighing packages.	QCP	Volume as per label	What: product How: weight Where: carton line When: half hourly Who: operator	Reject: all under weight packages and rework. Check and adjust filler, package capacity.	Log sheet No.1
8. Storage & Dispatch	Growth of bacteria	Keep refrigerated.	CCP5	≤ 4ºC	What: packaged product How: thermometer Where: coldroom When: continuously Who: operator	Reject: >10ºC for 5 hours and grade of milk poor.	Chart recorder
Key CCP = Critical Control Point (must do), QCP = Quality Control Point (must do for quality of product or regulatory requirement) CP = Control Point							

VERIFICATION SCHEDULE – Example only

ACTIVITY	DESCRIPTION	FREQUENCY	WHO	RECORDS	CORRECTIVE ACTION
Review of records	Production & Cool Room Logs	Daily	Owner	Logs signed off	If logs incomplete rectify and sign off.
Internal Microbial, Chemical and physical Testing	**Finished product from each batch to be tested for:-**				
	Coli < 10/mL	Daily	Owner	Lab report	Check cleaning system and monitor test results.
	E.coli not detected	Daily	Owner	Lab report	If >10 cfu/mL recall product
	TPC <20,000/mL*	Daily	Owner	Lab report	Check cleaning system and monitor test results.
	Phosphatase <10µg/mL of p-nitrophenol	Daily	Owner	Lab report	Product not released for sale and re-pasteurise or dump product.
	Fat >3.2%**	Daily	Owner	Lab report	Standardise milk to meet minimum standard
	Protein >3.0% crude (SNF >8.5%)**				
	Freezing point □-0.517^{0}C**				
	Antibiotics <0.003µg/mL penicillin	Daily	Owner	Lab report	Milk not to be used and investigate.
External Micro & Chemical Check Testing (at a NATA Lab)	Listeria not detected	Fortnightly	Owner	Lab report	Notify TDIA. Place all stock on hold/recall product released for sale. Follow clearance procedures as per the Listeria Manual
	Coli < 1/mL	Fortnightly	Owner	Lab report	If coli >10cfu/mL confirm and if E.coli. >10cfu/mL recall product.
	Phosphatase <10µg/mL of p-nitrophenol	Monthly	Owner	Lab report	If out of specification product must be recalled and other product and procedures checked.
	Antibiotics <0.003µg/mL penicillin				
Water Testing (at a NATA Lab)	Sample water used on product contact surfaces / cleaning for:- • coli nil per 100mL • E coli nil per 100mL	Monthly	Owner	Lab report	Check treatment procedures and retest immediately.
Verify Process Flow Diagram	• Follow process diagram through a production run.	Annual	Owner	Reissued documents	Amend practices or quality system
Review hazards	• Review customer complaints	Monthly	Owner	Complaints records	

ACTIVITY	DESCRIPTION	FREQUENCY	WHO	RECORDS	CORRECTIVE ACTION
Review HACCP plan	• Audit process flow diagram/HACCP charts	Annually – or as indicated	Owner	Audit reports	
Review hazard analysis	• Revisit original documentation to ensure information is still valid.	Annual	Owner	Diary entry	
Review critical limits	• Reassess critical limits after review of hazards	Annual	Owner	Reissued documents	
Calibration	• Review records to ensure control/compliance	As per calibration schedule	Owner	Calibration sheets signed as acceptable	

KEY

* Optional
** Dependant on product type