



Operational Guideline

Dairy HACCP Plans

May 2003

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1. What is the purpose of this guideline?

This guideline is designed to assist manufacturers operating under a Product Safety Programme (PSP)/Risk Management Programme (RMP) and other interested parties (e.g. Compliance and Investigation Group (CIG), Third Party Agencies (TPAs)) in the practical implementation of the NZFSA Standard D110.2, "Dairy HACCP Plans".

Specifically the purpose of this guideline is to assist in the:

- development of a Hazard Identification and Analyses or HACCP Plan for operation(s) covered by a PSP/RMP;
- assessment of Hazard Identification and Analyses or HACCP Plans.

2. What is included in this guideline?

This is a NZFSA: Dairy and Plant Products Group operational guideline. It includes:

- guidance material to assist in development and implementation of Hazard Identification and Analyses or HACCP Plans in accordance with NZFSA Standard D110, "Dairy HACCP Plans"

3. What are the desired outcomes?

It is expected that after reading this guideline all users of the NZFSA Dairy Standard D110, "Dairy HACCP Plans" will have a better understanding of how to develop and/or assess a Hazard Identification and Analyses or HACCP Plan for operations covered by a PSP/RMP.

4. Glossary of terms

NZFSA: Dairy and Plants Group definitions of terms can be found in their "Glossary of Terms" available on the Dairy and Plants website (www.nzfsa.govt.nz/dairy).

These definitions must be read in conjunction with the interpretations in the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*.

5. Frequently asked questions

Q. Where can information be found on HACCP?

A. Codex website (<http://www.fao.org/docrep/W8088E/w8088e00.htm>).

Q. What is the difference between a Hazard Identification and Analysis and a HACCP Plan?

A. A Hazard Identification and Analysis must be carried out on all processes that are covered by a PSP i.e. factories, stores and transporters. If one or more CCP is identified then other steps relating to CCPs must be put in place; this results in a HACCP Plan. In other words, if the Hazard Identification and Analysis does not identify any CCPs, steps 8.0, 9.0, and 10.0 are skipped. If CCPs are identified a HACCP Plan is put in place. In both cases all the documentation must be available for audit, to prove that the process has been followed.

- For Hazard Identification and Analysis the HACCP principles are followed, but no CCPs are identified after CCP determination. Process controls are required to control hazards that may be present. These controls may be part of prerequisite programmes, or operating parameters for the process. The following shows the applicable sections of Appendix One of D110.2, "Dairy HACCP Plans" for a Hazard Identification and Analysis:

Development and application of Hazard Identification and Analyses or HACCP Plans

- 1.0 Requirements prior to HACCP.
- 2.0 Describe product.
- 3.0 Identify intended use/intended consumer.
- 4.0 Construct flow diagram.
- 5.0 On-site confirmation of flow diagram.
- 6.0 Hazard identification, hazard analysis and control measures.
- 7.0 Determine whether Critical Control Points exist.
- 11.0 Establish verification procedures.
- 12.0 Establish documentation and record keeping.
- 13.0 Implementation.
- 14.0 Reporting.

- For a HACCP Plan the operation follows the HACCP principles and identifies CCPs. The following shows the applicable sections of Appendix One of D110.2, "Dairy HACCP Plans" for a HACCP Plan:

Development and application of Hazard Identification and Analyses or HACCP Plans.

- 1.0 Requirements prior to HACCP.
- 2.0 Describe product.
- 3.0 Identify intended use/intended consumer.
- 4.0 Construct flow diagram.
- 5.0 On-site confirmation of flow diagram.
- 6.0 Hazard identification, hazard analysis and control measures.
- 7.0 Determine whether critical control points exist.
- 8.0 Establish critical limits for each CCP.
- 9.0 Establish a monitoring system for each CCP.
- 10.0 Establish corrective actions.
- 11.0 Establish verification procedures.
- 12.0 Establish documentation and record keeping.
- 13.0 Implementation.
- 14.0 Reporting.

- Q. Is a Hazard Identification and Analysis needed, or a HACCP Plan?**
- A. Every process needs a Hazard Identification and Analysis, but not every process will need a HACCP Plan. Only where CCPs are identified is a HACCP Plan required.
- Q. Where and when does the Australia New Zealand Food Standards Code apply and when does it need to be complied with? Do both the ANZ Food Standards Code and D107, “Dairy Product Safety” need to be complied with?**
- A. The ANZ Food Standards Code is treated as a market access requirement for Australia and New Zealand. If product is being sold into those markets then the ANZ Food Standards Code must be complied with as well as D107.
- Q. Where does D107, “Dairy Product Safety” apply?**
- A. Everyone
- who manufactures, transports, stores, or exports any dairy product;
 - who is responsible for determining the conformance of dairy products to meet product safety outcomes;
 - who develops, evaluates or approves PSP/FSP/RMP;
- must comply with this Standard.
- Q. How are product outcomes determined?**
- A. The setting of product outcomes should ensure safe food. The product outcomes for particular products can be determined in the following ways:
- meeting the requirements of D107, “Dairy Product Safety”;
 - meeting any market access or customer specifications;
 - a company choosing their own product outcomes.
- Q. What sort of foreign matter needs to be considered?**
- A. All foreign matter that may be a food safety risk needs to be considered. Refer to D107, “Dairy Product Safety” for further information on foreign matter.
- Q. What is the relationship between the PSP/RMP and the Hazard Identification and Analysis/HACCP Plan.**
- A. The Hazard Identification and Analysis/HACCP Plan is an important component of the PSP/RMP. It is not a stand-alone document.

6 Guidelines

6.1 Development and application of Hazard Identification and Analysis, or HACCP Plans

All Hazard Identification and Analysis, or HACCP Plans, are developed in accordance with the Codex document entitled, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application". The details of this document are included, *in bold italics*, in Appendix One, "Acceptable Criteria" of D110.2 "Dairy HACCP Plans" and for clarification repeated in this Guideline.

6.2 Requirements prior to HACCP

HACCP is not a stand-alone programme but is part of a larger control system which builds on a series of prerequisite programmes. Therefore, prior to implementation of a Hazard Identification and Analyses or HACCP Plan, there is a requirement for the organisation to develop and implement applicable prerequisite programmes and other supporting systems.

Prerequisite programmes provide the basic environment and operating conditions that are 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.

There is a need to understand the role of prerequisite programmes in the prevention or control of common hazards. In addition, it is important to verify the effectiveness of prerequisite programmes to ensure that they effectively manage the common issues not considered in the Hazard Identification and Analyses or HACCP Plan.

Some prerequisite programmes are actually processes and therefore may have a critical influence at a specific step within the Hazard Identification and Analyses or HACCP Plan. When this occurs, that element would be included in the Hazard Identification and Analyses or HACCP Plan or subjected to the HACCP process separately e.g. factory water in accordance with MAF Standard D113, "Dairy Factory Water" etc.

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

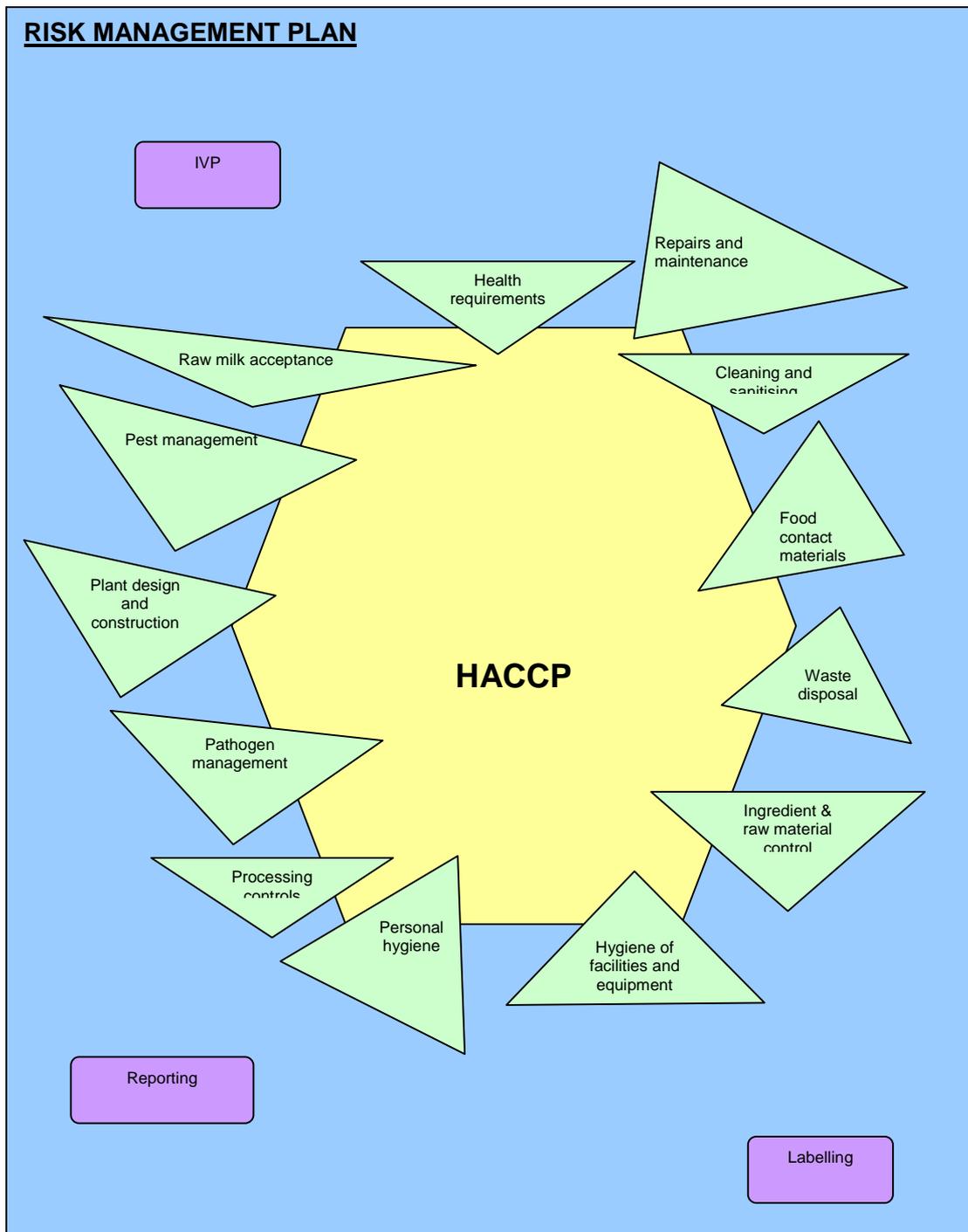
- personal hygiene requirements including protective clothing requirements, red-lines, personal equipment and use of amenities (refer MAF Standard D101, "Product Safety Programmes");
- health requirements e.g. procedures for staff diagnosed with a communicable disease (refer MAF Standard D101);
- food contact materials e.g. food grade products (refer MAF Standard D101);
- repairs and maintenance, including intrusive maintenance (refer MAF Standard D101);
- cleaning and sanitising programmes (refer MAF Standard D101);
- waste disposal (refer MAF Standard D101);
- pest management plans (refer MAF Standard D101);
- raw milk acceptance (refer MAF Standard D115, "Performance Measurement of Dairy Manufacturers" and MAF Standard D101);
- ingredient and raw material control (refer MAF Standard D101);
- processing controls e.g. chilling and storage temperatures (refer MAF Standard D101);
- plant design and construction, including ventilation (refer MAF Standard D202, "Registration of Dairy Premises" and MAF Standard MRD-Stan 8, "Maintaining and Restarting Non-Operating Dairy Factories and Stores");

- hygiene of facilities and equipment (refer MAF Standard D202 and MAF Standard D101).

In addition to the Hazard Identification and Analysis/HACCP Plan requirements, other systems should be developed when necessary as part of the PSP/RMP. These are simply tools (or in some cases regulatory requirements) that form part of the overall PSP/RMP but do not directly control hazards. These include, for example, but are not limited to:

- labelling (refer NZFSA Standard D103, “Labelling of Dairy Products”);
- reporting (refer NZFSA Standard D102, “Product Safety Reporting Requirements”); and
- Independent Verification Programme (refer NZFSA Standard D205, “Independent Verification Programme”).

A diagrammatic representation of the inter-relationships between supporting systems, HACCP and the RMP.



6.3 Assemble HACCP team

“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 method of introducing and working through the principles of HACCP will vary. The most popular method is through the assembly of a HACCP team whose role is to facilitate the process at the premises.

It is essential that the HACCP team has the right blend of expertise for the product(s) and/or process being considered. Typically, the types of people involved may include engineers, microbiologists, production and/or quality control staff.

6.4 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 objective of a Hazard Identification and Analysis/HACCP Plan is to ensure control of hazards that are significant for food safety within the defined boundaries of the process under consideration.

Smaller premises, e.g. those producing a single product, may choose to develop all of the Hazard Identification and Analysis/HACCP Plan in one step i.e. the scope of a single Hazard Identification and Analysis/HACCP Plan covers the whole operation. Larger operations may choose to divide their process into a number of smaller modules that can be progressively developed.

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

- start and end point of the Hazard Identification and Analysis/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 Hazard Identification and Analysis/HACCP Plan;
- specific activities that are not covered in the prerequisite programmes or other Hazard Identification and Analysis/HACCP Plans e.g. rework, etc.
- classes of hazards addressed by the Hazard Identification and Analysis/HACCP Plan.

6.4.1 Describe product

“A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w , 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 and while other non food safety parameters may be included, they are outside the scope of the Standard.

6.4.2 Identify intended use and intended consumer

“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. appropriate 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.

6.5 Product outcomes

The HACCP team must determine what the organisation intends to achieve in terms of product safety outcomes for each product.

When deciding on product outcomes, the HACCP team should consider what “Safe Product” actually means for the particular product and process in question. Additionally, market access/customer expectations should be considered.

Where two or more product safety limits apply, the product outcome should be based on the tighter limit e.g. the limit for *Bacillus cereus* in powdered infant formula.

Standard	Product Safety Limit (PSL)			
MAF Standard D107, “Dairy Product Safety”				
<i>Bacillus cereus</i> – specific PSL	100/g			
Australia New Zealand Food Standards Code (ANZ FSC)	n	c	m	M
<i>Bacillus cereus</i> /g	5	2	10	100

The product outcome for *Bacillus cereus* stipulated in the ANZ FSC is tighter than that in MAF D107, “Dairy Product Safety” and therefore the ANZ FSC product outcome applies.

Product outcomes specify the level of hazard control achievable at the end of manufacture. They should be measurable and can relate to individual hazards or groups of hazards. While these outcomes reflect the control of specific hazards, they may also reflect the control of parameters accepted as indicators of hazards e.g. presence/absence of *E. coli* as an indicator of enteric pathogen control etc.

Product outcomes should be reviewed at the completion of the Hazard Identification and Analysis and CCP sections to ensure that these are compatible with the expected product outcomes. In summary, the documentation of product outcomes offers the following benefits:

- a quantitative target for the design of a Hazard Identification and Analysis or HACCP Plan, allowing effective measurement of the expected product outcomes, thereby assisting in the verification process;
- provision of a means for assessing equivalence of food safety systems, e.g. for market access;
- clear identification of the limitations of a Hazard Identification and Analysis or HACCP Plan.

6.6 Construct flow diagram

“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 Hazard Identification and Analyses or 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. Where trials have the potential to impact on mainstream processes, their impact should also be subject to a hazard analysis.

6.7 On-Site Confirmation Of Flow Diagram

“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, the process flow diagram should be confirmed.

It is recommended the process flow confirmation includes:

- a physical walk 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.

6.8 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 (SEE PRINCIPLE 1).”

A thorough hazard analysis is essential in preparing an effective Hazard Identification and Analysis/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;
- identify any required modifications to a product or process to provide a greater food safety assurance;
- provide a basis for determining the process critical control points (See Principle 2).

6.8.1 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.

At this point of the analysis, the hazard source should be identified and where appropriate, the actual hazard should be stated in specific terms. The level of specificity and detail is determined by the extent of hazard identification required to ensure effective hazard control. For example the hazard description, "Biological hazard in milk" is not specific or detailed enough. The description would better be, "Pathogenic bacteria, e.g. *E. coli*, *Listeria monocytogenes*, *Salmonella* spp., *Staphylococcus aureus* in raw milk". This will ensure that the control measures are relevant and effective in controlling the specific hazard(s) identified.

In order to assess the likelihood or probability of the hazard occurring, a combination of experience, information from technical literature etc. may be useful. For example, there is a higher probability of manufacturing unsafe pasteurised chocolate milk from cocoa powder containing high *Bacillus cereus* spore counts ($>10^2$ cfu/g).

6.8.2 Conduct a hazard analysis

"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 effects¹;***
- ***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. Where possible, these analyses should be based on:

- **Severity of health consequences** i.e. seriousness of the consequences of exposure to the hazard.

For example, *Bacillus cereus* causes a foodborne infection that can result in moderate to severe illness depending on the number of cells ingested (evidence indicates that the diarrhoeal illness is caused by the consumption of moderate to high numbers of organisms and the production of the toxin *in vivo*).

- **Qualitative or quantitative analysis of the presence of hazards.**

¹ The likely occurrence of hazards and severity of their adverse health effects means the probability of occurrence and severity of illness.

The quality and/or quantity of each hazard that may occur in the process should be compared to the designated product outcome to ensure the production of safe food.

For qualitative analysis, variations in hazard quality will affect hazard significance e.g.:

- For physical hazards product contamination with rubber may not be as significant as glass.
- For biological hazards the effects of processing and storage may impact on microbial cell quality due to injury. This must be considered when assessing the microbial quality of products. If the injury is ignored, results could indicate low counts when in fact the product contains a high number of cells which simply have not been shown by the technique used.

For quantitative analysis, the number or amount of a hazard which may cause illness or injury should be taken into consideration e.g. the infectious dose for pathogenic bacteria vary; a product containing 950cfu/g *Bacillus cereus* may be safe whereas the same product containing a few *Salmonella* cells may not.

- **Survival or multiplication of micro-organisms of concern.**

Process steps designed to reduce the concentration of micro-organisms should be assessed for their effectiveness e.g. chocolate milk containing high levels of *Bacillus cereus* spores processed through a pasteuriser operating at 72°C/15 seconds will not destroy the spores (approximate times for 1D kill for *Bacillus cereus* spores is 110°C for 6 seconds). Additionally, process conditions should also be assessed for their effect on micro-organism growth rates e.g. *Bacillus cereus* sporeformers can grow from 10²cfu/ml to 10⁴cfu/ml during processing and storage.

- **Production or persistence in foods of toxins, chemicals or physical agents.**

Chemical and physical agents may remain in a product during processing despite various control measures e.g. filtering of physical contaminants.

Favourable growth conditions may result in the production of toxin in the product e.g. *Bacillus cereus* may produce diarrhoeal enterotoxin.

During the analysis of each potential hazard, the product, its method of preparation, transportation, storage and likely consumers should be considered to determine how each of the above factors may influence the hazard significance. It should be noted that differences of opinion regarding hazard significance are common because ingredient sources, formulations, processing equipment and methods, duration of processes, storage conditions and experience and knowledge of personnel may vary. For example, due to differences in equipment and/or an effective maintenance programme, the probability of metal contamination may be significant in one manufacturing plant but not in another.

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.

Product outcomes may need to be reviewed after hazard analysis as there may be hazards that are there that need outcomes.

6.8.3 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 programme. 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.

6.9 Determine critical control points (SEE PRINCIPLE 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. An “acceptable level” is the level determined in section 3.0, “Outcomes” of NZFSA Standard D110.2, “Dairy HACCP Plans”. The most practical designation of a CCP is a process step.

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 (see figure 6.9.1). 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.

An example of this is in some hard cheese manufacture, where there are two CCPs required to meet the product outcome. Thermisation and ripening² are used together as follows:

² Information taken from the “Interim Code of Practice for the development of a Food Safety Programme or a Product Safety Programme for Specialist Cheeses” draft, 29 April 2002.

- Thermisation

Thermisation is only available as an option for the production of hard cheeses and must always be accompanied by another CCP at **ripening** in order to meet the product outcomes.

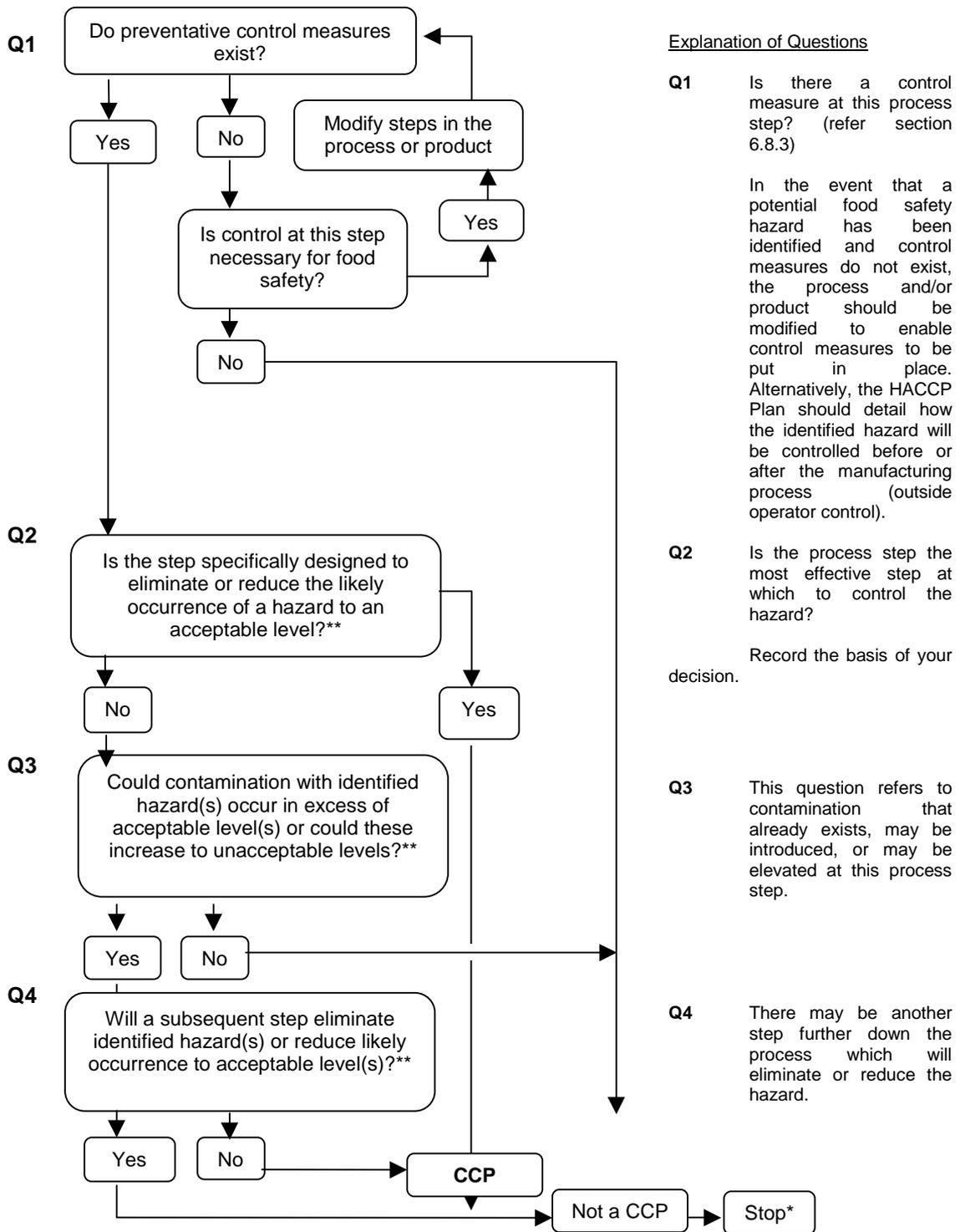
The thermisation temperature/time requirement is **64.4°C** for not less than **15** seconds. It is known that the acceptable level of control of the biological hazards at this point will be that some pathogens will be killed but not all. This CCP on its own will not meet the product outcome.

- Ripening

This is a CCP only in association with **thermisation** and **hard cheese** varieties. The critical limits for ripening are not less than 90 days at not less than 2°C. The combined effects of these two CCPs achieves the product outcome.

Remember that hazards controlled in the HACCP Plan should only be those hazards which are of such a nature that their prevention, elimination or reduction to acceptable levels is essential for the production of safe food.

Fig 6.9.1 Codex Alimentarius Decision Tree to Identify CCPs



* Proceed to the next identified hazard in the described process.

** Acceptable levels (and conversely, unacceptable levels) are determined in relation to the product outcome required for a particular hazard.

6.10 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. They are specific to the CCP itself and should not be confused with a product outcome acceptable level e.g. for general population:

Pasteurisation	
Critical Limits	72°C/15secs ³
Product Outcome	Refer to D107, “Dairy Product Safety” for limits

When the critical limits for a critical control point have been met, (in the example above, 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”.

The critical limits must be measurable, achievable and appropriate to the CCP and hazard(s) being controlled and wherever possible, there should be a scientific basis for the control process and the limits set for each CCP. This information may be found in scientific publications, challenge studies (these must be properly designed to show the destruction, elimination or control of the hazard concerned) and government regulatory agency standards and guidelines.

It is important when setting critical control point limits, the variability of any monitoring equipment or process should be considered. The rationale for selected critical limits should be documented.

Once the critical limits have been determined they should be proven (“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.

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” and allow early action to be taken by the manufacturer to avoid the production of unsafe product. They should not however, be confused with critical limits.

6.11 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

³ This is an example only; there are other time/temperature combinations for pasteurization (refer to NZFSA Standard D121, “Dairy Heat Treatments”).

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);
- frequency of the monitoring including statistically valid sampling regimes;
- what will be monitored;
- where monitoring will occur; and
- how critical limits will be monitored.

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 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 should sign records, e.g. the shift supervisor reviews and signs the records daily.

6.12 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 MAF Standards D108, “Non-conforming Dairy Produce” and D102, “Product Safety Programme Reporting Requirements”.
- 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.

6.13 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.

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities, as monitoring information is required quickly to ensure CCPs are under control.

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.

6.13.1 Hazard Identification and Analyses or HACCP Plan validation

The Hazard Identification and Analyses or 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 Hazard Identification and Analyses or HACCP Plan are effective in achieving the product outcomes. Hazard Identification and Analyses or 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 (e.g. heat treatment in accordance with NZFSA Standard D121, “Dairy Heat Treatments”, 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.

(**Note:** CCP monitoring and corrective action apply to a HACCP Plan only).

6.13.2 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 Hazard Identification and Analyses or HACCP Plans or selected parts. A full review is recommended periodically to ensure that the Hazard Identification and Analysis or 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 Hazard Identification and Analysis or HACCP Plans

Additionally, a review of the HACCP system should occur when changes that may impact on the Hazard Identification and Analysis or 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.

6.13.3 Equipment calibration

The calibration of CCP process monitoring instruments needs to be:

- at a frequency to assure continuous accuracy;
- according to procedures established in the HACCP Plan;
- against a recognised standard.

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

6.13.4 Product sampling and testing

Product sampling and testing is used to verify that the product outcomes of the HACCP Plan have been met.

The product sampling and testing regime that is used to verify the product outcomes of the HACCP Plan have been met, shall be recorded, validated and available for audit.

Sampling and testing regimes will depend upon whether the product has been manufactured using a batch or continuous process.

- **Batch Process**

A batch lot is usually defined as a definite quantity of dairy product of a single composition, manufactured or produced under conditions which are presumed uniform, and from which a sample or samples are to be drawn and inspected to determine compliance with the acceptability criteria.

Where the product has been manufactured using a batch process, the following parameters should be considered when determining an appropriate sampling and testing rate:

- **Product Type**

The inherent safety of a product, which is determined by its characteristics, will influence whether it is likely to contain and/or support potential pathogen growth. For example, products such as edible dairy oils which have a low A_w are microbiologically safe and therefore likely to have lower pathogen sampling and testing rates in comparison to products such as pasteurised liquid milk which present an ideal medium for pathogen growth.

- **Process Type**

Manufacturing processes have the potential to impact on the safety of the product through the introduction of hazards and, in some instances, present conditions that may lead to the survival or multiplication of micro-organisms and/or production or persistence of toxins, chemicals or physical substances. Each process will differ in the hazards it presents to the final product and therefore a thorough understanding of how the product is processed is required. For example, UHT/aseptically packaged products will not require sampling and testing for pathogenic micro-organisms providing the commercial sterility test is clear.

- **In-Process Sampling and Testing**

For those manufacturing processes where a comprehensive in-process sampling and testing regime is in place, a reduced level of final product verification sampling and testing may be appropriate.

Additionally, indicator organisms may be used to indicate the risk of product contamination by pathogens. Specific indicators such as coliforms are used to reveal unsanitary manufacturing processes, unsuitable time/temperature conditions or process failure in some instances.

- **Historical Performance**

For those processing plants which have historically performed well, a reduced sampling and testing regime may be appropriate. Process design and the capability of the process to operate within suitable tolerances will impact on sampling and testing rates.

- Review hazards identified and the level of hazard control achieved

Consider the hazards identified in the original analysis and determine using the sampling and testing regime whether the controls are working effectively on a consistent basis.

- **Continuous Process**

Where the product has been manufactured using a continuous process, the parameters considered for a batch process also apply. In addition, sampling plans for continuous processes should be statistically based.

- **Additional Testing Requirements**

In the event of a non-routine event, consideration must also be given to whether additional sampling and testing is required to verify whether the product outcomes are still being met. Non-routine events may include:

- areas outside the normal process variability e.g. where a concentrate heater that normally operates within $80\pm 5^{\circ}\text{C}$ range drops to 65°C during manufacture may present an increased product risk in terms of pathogen growth;
- processing plant breakdowns or other conditions that lead to the multiplication of pathogens;
- Prerequisite Programme failure in a verified Prerequisite Programme may adversely impact on the safety of a product e.g. building integrity is compromised and product may be put at risk when rain water flows into a dried powder packing room;
- non-compliance to NZFSA Dairy requirements potentially impacting on product safety.

Where a non-routine event has occurred, the affected product must be identified and an assessment of both product attributes and the frequency at which these attributes are to be sampled and tested must be made.

The results of all product safety testing must meet the designated product outcomes irrespective of how or why the testing was initiated.

- **Final Product Sampling and Testing**

Where final product sampling and testing is undertaken for verification, it must comply with the following:

- 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. Guidance on sampling techniques can be obtained from IDF Standard 50C: 1995, "Milk and Milk Products Guidance on Sampling".
- All finished product testing for the purposes of the determination of safety should be undertaken using an NZFSA-approved test method for the attribute being tested. A list of NZFSA-approved test methods can be obtained from the NZFSA Dairy & Plants website.
- All finished product testing should be undertaken in a NZFSA registered laboratory accredited or recognised in the appropriate category for the required test (refer to MAF Standard D302, "Registration of Dairy Laboratories").

- Resampling and retesting of product does not occur except in accordance with the requirements for control of non-conforming testing and/or calibration work specified in ISO/IEC Standard 17025, "General Requirements for the Competence of Testing and Calibration Laboratories" and MAF Standard D107, "Dairy Product Safety".

Documentation and record keeping should be undertaken in accordance with the requirements detailed in MAF Standard D101, "Product Safety Programmes".

6.14 Establish 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."

Documentation examples are:

- ***Hazard analysis;***
- ***CCP determination;***
- ***Critical limit determination.***

Record examples are:

- ***CCP monitoring activities;***
- ***Deviations and associated corrective actions;***
- ***Modifications to the HACCP system."***

Records are essential for reviewing the adequacy of the HACCP Plan and the compliance of the HACCP system to the Plan. As a minimum the following documentation should be kept:

- HACCP Plan and the support documentation used to develop the plan e.g. data used to establish the adequacy of the critical limits in ensuring the safety of the product or data used to establish sampling and testing rates;
- Hazard Identification and Analysis data;
- CCP determination process;
- CCP monitoring records e.g. temperature, time etc.;
- Corrective Action Records (including product disposition records);
- Verification Activity Records e.g. sampling and testing regimes;
- Verification records, e.g. audit reports, etc.

Documentation and record keeping should be undertaken in accordance with the requirements detailed in MAF Standard D101, "Product Safety Programmes".

6.15 Training

"Training of personnel in industry, government and academia 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."

A staff training programme on HACCP should be established in accordance with the ongoing expectations of the company. This should include HACCP awareness training for senior management, managers, supervisors, technical staff and process staff and specific HACCP training for key personnel.

There are a number of ways that a Hazard Identification and Analyses or HACCP Plan can be implemented. This will depend on the size and complexity of the operation and resources available. The company must decide the best way to introduce the plan to the workplace.

For the Hazard Identification and Analyses or 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.

To enhance the HACCP training the following are useful reading resources:

- NZFSA Standard D110, "Dairy HACCP Plans"
- Codex website (www.fao.org/docrep/W8088E/w8088e00.htm)
- Dairy Industry Training Organisation (www.nzito.co.nz).

It is important that HACCP responsibilities are considered. Responsibilities associated with implementation of the Hazard Identification and Analyses or HACCP Plan need to be delegated to persons covering all shifts and days of the operation. An up-to-date log should be kept of all CCPs indicating those people responsible for monitoring and taking corrective actions. All persons responsible for implementing the Hazard Identification and Analyses or HACCP Plan need to clearly understand the criteria for control, including monitoring procedures, resources needed and corrective actions to be taken.

6.16 External assessment of Hazard Identification and Analysis/HACCP Plan

6.16.1 Evaluation of Hazard Identification and Analysis/HACCP Plans

The validated Hazard Identification and Analyses or HACCP Plan is evaluated by MAF CIG/an approved TPA when it is first developed and following all significant changes. The technical competencies of evaluators are detailed in MAF Standard D503, "Third Party Agencies' Responsibilities".

6.16.2 External verification of Hazard Identification and Analysis/HACCP Plans

MAF CIG/an approved TPA verifies the Hazard Identification and Analyses or HACCP Plan when the PSP is verified. The technical competencies of evaluators are detailed in MAF Standard D503, "Third Party Agencies' Responsibilities".

6.17 Reporting

Records and reporting should be undertaken as required by MAF Standard D101, "Product Safety Programmes" and MAF Standard D102, "Product Safety Reporting".

7. For more information or comments on this guideline

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