

New Zealand Food Safety Authority
P O Box 2526, Wellington, New Zealand

NZFSA: Dairy & Plants Standard

Circular number 76
Dairy Industry Regulations 1990

D110.2 Dairy HACCP Plans

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110.2	15 May 2003	Promulgated by Circular number 76	Director, NZFSA Dairy and Plants	

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Issue of Circular and implementation

Regulation 59 of the *Dairy Industry Regulations 1990* allows the Director-General of the New Zealand Food Safety Authority to issue Circulars setting out criteria for matters which must be approved by, or done to the satisfaction of, the Director-General, pursuant to the *Dairy Industry Regulations 1990*.

This Circular, no. 76, containing NZFSA Standard D110.2, "Dairy HACCP Plans" is issued in accordance with that regulation 59.

This Circular, no. 76, takes effect on 15 May 2003.

This Standard will apply to all new Product Safety Programmes (PSPs) from the date of issue by Circular.


Existing PSPs approved under the previous regulatory requirements will need to comply with this Standard twelve months from the date of issue. Amendments to currently approved PSPs to incorporate the requirements of this Standard will require validation prior to evaluation by NZFSA/Third Party Agencies (TPAs) and approval by NZFSA.

Approval for the following NZFSA standards is withdrawn:

- MAF Standard D109.1, Dairy Product Conformance,
- MAF Standard D110.1, "Dairy HACCP Plans".

Circular number 46, containing MAF Standard D109.1, "Dairy Product Conformance", is revoked.

Circular number 47, containing MAF Standard D110.1, "Dairy HACCP Plans", is revoked.



Tim Knox
Director, Dairy and Plant Products
New Zealand Food Safety Authority
15 May 2003

(Signed under authority delegated by the Director-General of NZFSA, pursuant to regulation 59 of the Dairy Industry Regulations 1990.)

Foreword

Under the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*, NZFSA is responsible for establishing an adequate framework to provide assurances that dairy products manufactured in New Zealand are safe. Development of Hazard Analysis and Critical Control Point (HACCP) Plans as part of a Dairy product safety programme (PSP) is a key step in achieving this objective.

NZFSA standards are intended to assist the industry by interpreting the regulatory requirements, and indicating acceptable criteria for complying with the requirements and verifying compliance.

The NZFSA Standard D110.2, "Dairy HACCP Plans" was developed to specify how the HACCP principles and guidelines are used to develop Hazard Identification and Analyses or HACCP Plans that are components of Product Safety Programmes (PSPs).

This Standard sets out the outcomes specified in the *Dairy Industry Regulations 1990* relating to the development of Hazard Identification and Analyses or HACCP Plans for incorporation into a PSP to ensure that dairy produce manufactured, transported and stored in accordance with the PSP is safe.

The purpose of this Standard is to ensure the application of HACCP to manage food safety. Although not mandatory, at the discretion of the manufacturer, the HACCP application may be widened to include non-food safety issues.

The acceptable criteria outlined in Appendix One of this Standard were developed in consultation with industry to establish clear rules for judging whether or not a proposed PSP is satisfactory, and to assist parties to achieve the outcomes described in the Standard. Proposals for alternative criteria will be approved by NZFSA, provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved.

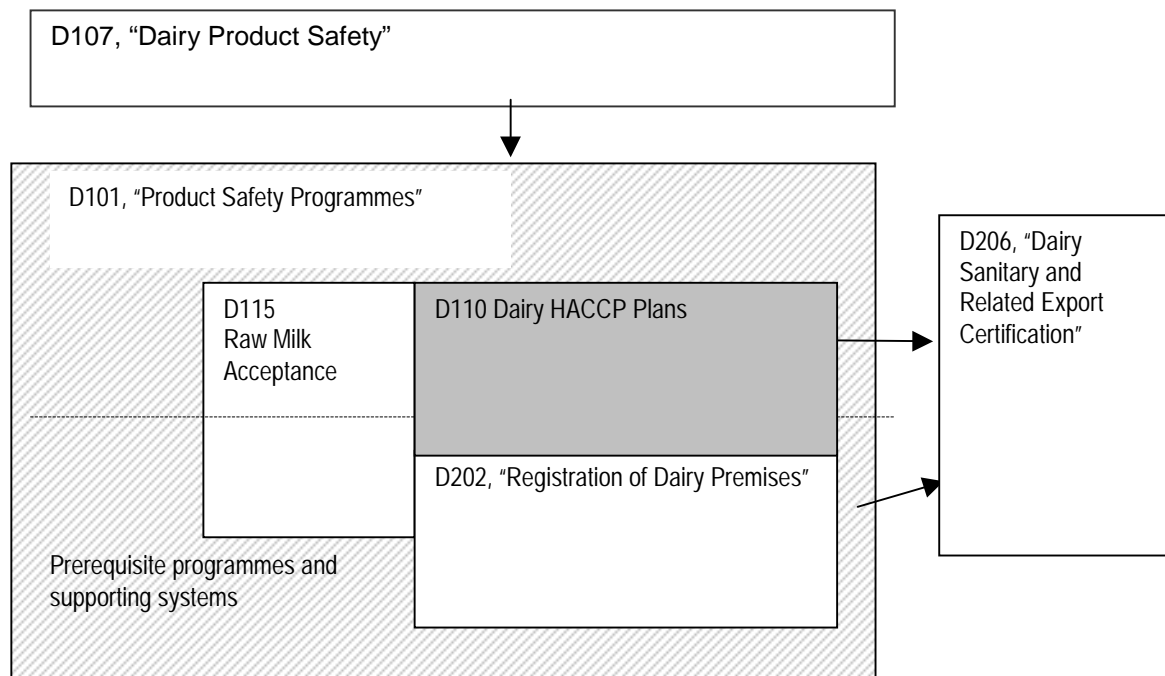
In addition, appendices to this Standard provide:

- the criteria used to assess whether the outcomes contained in the Standard are met;
- importing country requirements relating to official assurances provided by NZFSA concerning HACCP Plans.

Preface

Context

This Standard relates to other NZFSA Standards as shown diagrammatically below.



Resources

The following standards must be read in conjunction with this Standard:

- MAF Standard D101, "Product Safety Programmes".
- MAF Standard D102, "Product Safety Programme Reporting Requirements".
- MAF Standard D201, "Performance Measurement of Dairy Manufacturers".
- NZFSA Standard D107, "Dairy Product Safety".
- MAF Standard D113, "Dairy Factory Water".
- MAF Standard D108, "Non-conforming Dairy Produce".
- NZFSA Standard D121, "Dairy Heat Treatments".

Additional documents that may be useful resources:

- NZFSA Food: Dairy operational guideline, "Dairy HACCP Plan Guideline" provides information to assist in meeting the outcomes required by this Standard. A copy of this guideline can be obtained from the NZFSA website www.nzfsa.govt.nz/dairy/publications/guidelines/.
- "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application," Supplement to Volume 1B, Annex to CAC/RCP 1-1969, Rev 3 (1997). Codex Alimentarius Commission, 1997. Website address: ftp://ftp.fao.org/codex/standard/en/CXP_001e.pdf

Effective changes

This Standard will introduce the following changes to the previously existing situation:

- inclusion of requirements for determining product safety sampling and testing (previously contained in D109, "Dairy Product Conformance");
- inclusion of requirement for prerequisite programme(s) and other supporting systems;
- introduction of product outcomes;
- removal of Food Safety Objectives (FSOs).
- clarification of the difference between Hazard Identification and Analyses and HACCP Plans

Future intentions

Work has commenced on amending the *Animal Products Act 1999* (APA) to include dairy operations in the scope of that legislation. This legislation places an increasing emphasis on HACCP as the means of managing hazards, such as pathogenic micro-organisms, in human food and animal feeds. The validated HACCP Plan is the platform for an operator's Risk Management Programme (which is the APA version of a PSP).

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NZFSA Standard D110.2, “Dairy HACCP Plans”

1.0 Scope

This Standard defines the outcomes for the use of the Hazard Analysis and Critical Control Point (HACCP) principles and guidelines to develop Hazard Identification and Analyses or HACCP Plans that are components of a Product Safety Programmes (PSP), and required by NZFSA Standards to be incorporated into specific sections of the PSP.

This Standard applies to:

- all dairy product manufacturers, operators of dairy stores, and transporters of dairy produce (including product), applying for approval of PSPs, and
- all parties required by NZFSA Standards to incorporate HACCP Identification and Analyses/Plans into specific sections of the PSP.

Importing country and export certification requirements may place additional requirements on the HACCP Plan/Analyses. Further information is provided in Appendix Two.

2.0 Definitions

NZFSA Food: Dairy and Plant Products Group definitions of terms can be found in the “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*.

Accountable person - The person named in a NZFSA-approved PSP who is responsible for all operations covered by the PSP, and for ensuring that those operations comply with regulatory requirements.

Approved individual – A person who has demonstrated that they meet NZFSA competency standards for qualifications and experience, and has subsequently been approved by the Director-General of NZFSA pursuant to the *Dairy Industry Regulations 1990*.

Assessment - Systematic examination of an individual, organisation, plan, programme, or system against regulatory requirements.

Batch - 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.

Conflict of interest – Any circumstance that may undermine or detract from the impartiality and/or independence of an individual or organisation.

Corrective action – Action taken to rectify, eliminate the causes of, and prevent recurrence of any problem/failure/non-compliance identified in a plan, procedure, process, product, programme, or system.

Critical control point (CCP) – A step in a process at which a control can be applied which is essential to prevent, eliminate, or reduce a food safety hazard to an acceptable level.

Critical limit - A criterion which separates acceptability from unacceptability.

Critical non-compliance – An action, event or omission which may result in:

- failure of dairy produce to comply with regulatory requirements;
- failure to follow the lawful direction of an Inspector;

- an alleged offence against the *Dairy Industry Act 1952* or *Dairy Industry Regulations 1990*;
- a critical situation;
- failure of a critical control point within a NZFSA-approved programme or plan;
- failure to identify when dairy produce is non-conforming;
- failure to stop a non-compliance;
- failure to keep accurate and complete records;
- failure to provide accurate, complete, and timely reports;
- failure to dispose of non-conforming dairy produce in compliance with regulatory requirements;
- failure to prevent recurrence of a non-compliance; and/or
- failure to rectify a non-compliance within the specified timeframe.

Critical situation – Any situation which, in the professional judgement of the Inspector, places public health, animal welfare, market access, official assurances, national good or NZFSA's credibility at risk, or where an offence is suspected.

Dairy produce – Milk, cream, butter or cheese, and includes any other product of milk or cream.

Dairy product – Dairy produce intended for sale in, or export from, New Zealand for human consumption; and

- includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream; but
- does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

Evaluation - Assessment of an individual, plan, programme, or system to determine compliance with regulatory requirements. This will involve review of documentation and, in some cases, review of operations or observation of practice. It is undertaken by a competent individual contracted to an impartial agency (e.g. TPA or Assessor, NZFSA Compliance and Investigation Group).

HACCP - Hazard Analysis and Critical Control Point system adopted by the Codex Alimentarius Commission. HACCP is a systematic identification of hazards and the measures for their control to ensure the safety of food. It focuses on prevention rather than end-product testing.

Hazard – A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Identification and Analyses – A documented system prepared in accordance with the principles of HACCP but differing from a HACCP Plan because CCPs are not identified.

HACCP Plan - A documented system, prepared in accordance with all the principles of HACCP, to ensure control of significant food safety hazards in a food handling process. A HACCP Plan always includes CCPs.

Lot - A quantity of dairy product manufactured during a discrete period of time, not normally exceeding 24 hours, in one continuous process.

Monitor – In the context of a HACCP Plan, means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.

NZFSA Compliance – The Compliance and Investigation Group (CIG) of NZFSA, reporting to the Director, Compliance and Investigation Group.

NZFSA: Dairy & Plants – The Dairy and Plant Products Group of NZFSA, reporting to the Director, Dairy and Plant Products.

Prerequisite programme – A documented programme covering good manufacturing practice (GMP)-based food hygiene activities that may interact at a number of process steps within and across various processes in a food premise, and that have the potential to influence the hygiene status of the product and/or control hazards.

Product outcome - The expected level of hazard control relating to dairy product resulting from implementation of the Hazard Identification and Analyses or HACCP Plan (this definition is to be reviewed).

Product Safety Programme (PSP) – A programme of conditions, processes, procedures, measures, and standards to be complied with, performed, undertaken, taken, or met in relation to:

- (a) any process or activity related to dairy produce, ingredients used in the manufacture of dairy products, or both; and
 - (b) sampling, examination, inspection, and testing, or any of those actions, relating to any such process or activity; and
 - (c) the recording and inspection (by persons with qualifications and experience approved by the Director-General for the purpose) of information relating to any such action;
- and (without limiting the generality of the foregoing) may include conditions, processes, procedures, measures, or standards relating to the production, manufacture, storage, or transport of dairy produce.

Representative sample - A representative sample is one whose condition is as similar as possible to that from the lot from which it was drawn. Ideally the quality of a collection of sample units is neither better nor worse than that of the whole lot.

Safe - In relation to any dairy product, “safe” means satisfactory, fit for human consumption, and not having in it or on it any pathogenic organisms

- (a) that are present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; or
- (b) that
 - (i) are not present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; but
 - (ii) by virtue of their ability to reproduce, to produce toxins, or both, make the product potentially harmful or injurious to the health of the people who may eat or drink it.

In relation to any dairy produce that is not a dairy product, “safe” means satisfactory, and fit for the manufacture of dairy products.

Significant change – A change made to key staff, environment, premises, equipment, facilities, process or product that may affect food safety.

Supporting System - System used to support the overall ongoing compliance of the Hazard Identification and Analyses/HACCP Plan, but which does not necessarily influence the hygiene status of the product and/or control hazards.

Third Party Agency (TPA) - Organisation approved by NZFSA to carry out evaluation and/or verification services.

Validation – Assessment of a plan, programme or system that it is complete, is being implemented as documented, and is delivering the expected outcomes. It is undertaken by the owner of the plan, programme or system (this definition is to be reviewed).

Verification – Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with NZFSA-approved plans, programmes and systems, and to confirm the ongoing applicability of these.

3.0 Outcomes

The safety hazards for the manufacture, transport and storage of dairy produce are identified, controlled, monitored, verified and recorded, to satisfy the Director-General of NZFSA that dairy produce is safe, in compliance with regulation 6 of the *Dairy Industry Regulations 1990*.

Where NZFSA provides official assurances to international competent authorities, the relevant importing country requirements are demonstrated to be met.

3.1 HACCP Requirements

Every person who

- transports or stores any dairy produce that is not a dairy product; or
- manufactures, transports or stores any dairy product

must do so in accordance with a Product Safety Programme (PSP) approved by the Director-General of MAF. This includes validated Hazard Identification and Analyses or HACCP Plans of the processes covered by the PSP (PSP Hazard Identification and Analyses or HACCP Plans).

All Hazard Identification and Analyses/HACCP Plans required by NZFSA Standards must comply with the Codex document entitled “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application” – website address: ftp://ftp.fao.org/codex/standard/en/CXP_001e.pdf. The product outcomes must be documented as part of the hazard analysis.

This Standard requires the use of the HACCP principles and guidelines. When these are used the operation will take one of two paths depending on whether or not critical control points (CCPs) are identified. The paths are:

- the HACCP Plan where CCPs are identified; or
- Hazard Identification and Analyses where no CCPs are identified.

The detail is as follows:

1. HACCP Plan

The operation follows the HACCP principles and CCPs are identified. The following shows the applicable sections of Appendix One for this operation:

- 1.0 Requirements prior to HACCP.
- 2.0 Describe Product.
- 3.0 Identify Intended Use.
- 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 CCPs 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 Training.
- 14.0 External Assessment.

2. Hazard Identification and Analyses

The operation follows the HACCP principles up to Step 7.0 Determine CCPs. After CCP determination when no CCPs are identified steps 8.0, 9.0 and 10.0 are not required. The following shows the applicable sections of Appendix One for this operation:

- 1.0 Requirements prior to HACCP.
- 2.0 Describe Product.
- 3.0 Identify Intended Use.
- 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 CCPs exist.
- 11.0 Establish verification procedures.
- 12.0 Establish Documentation and Record Keeping.
- 13.0 Training.
- 14.0 External Assessment.

Where a HACCP Plan includes heat treatment as a critical control point for the control of pathogens, heat treatments are operated in accordance with NZFSA Standard D121, "Dairy Heat Treatments". www.nzfsa.govt.nz/dairy/publications/standards

Documented and effective prerequisite programmes, and other supporting systems, are essential to the success of any hazard identification or HACCP Plan, and are expected to be operating prior to implementing HACCP.

4.0 Evaluation

Evaluation of the Hazard Identification and Analyses or HACCP Plans is undertaken by NZFSA CIG or a NZFSA-approved TPA as part of a PSP evaluation as required by MAF Standard D101, "Product Safety Programmes".

5.0 Verification (external)

Verification of compliance with this Standard is undertaken by NZFSA CIG or a NZFSA-approved TPA as part of a PSP assessment, as required by MAF Standard D101, "Product Safety Programmes".

5.1 Compliance

The manufacturer is compliant with the outcomes described in section 3 of this Standard if:

- the means to deliver the outcomes described in section 3 of this Standard are documented in a NZFSA-approved Hazard Identification and Analyses or HACCP Plan that forms part of a PSP; and
- the parties operate in accordance with that NZFSA-approved PSP.

Parties operating in compliance with the outcomes described in section 3 of this Standard and a NZFSA approved PSP are entitled to:

- produce milk or cream intended for the manufacture of dairy products;
- transport or store dairy produce;
- manufacture, transport, or store dairy products for sale and/or export.

5.2 Non-compliance

The dairy manufacturer is non-compliant if one or more of the criteria in section 5.1 for assessing compliance are not met.

Non-compliance with the outcomes described in section 3 of this Standard (including selling or exporting dairy products not manufactured in accordance with an approved PSP) constitutes an offence under regulation 49 of the *Dairy Industry Regulations 1990*.

If a dairy manufacturer does not operate in accordance with the requirements in this Standard:

- a Notice may be issued by a NZFSA Inspector to remedy any defects;
- export certification and/or use of any NZFSA marks may be suspended;
- approval of the PSP/RMP may be withdrawn; and/or
- prosecution for this and other offences may occur.

Appendix One: Acceptable Criteria

NZFSA: Dairy and Plant Products Group recognises that a PSP holder can meet the outcomes in section 3 of the Standard in a number of different ways.

Following are criteria by which a dairy PSP holder may be judged to satisfactorily achieve the outcomes described in section 3 of this Standard. A Product Safety Programme (PSP) that includes procedures for ensuring that each of these criteria is satisfied and meets all other relevant PSP requirements will be approved by NZFSA.

The PSP holder may provide proposals for alternative criteria, which are other ways of delivering the outcomes in this Standard. NZFSA will approve these proposals provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by NZFSA to assess proposals can be obtained from NZFSA.

Similarly industry sectors may develop codes of practice that contain means of satisfying these criteria, and/or alternative means of achieving the outcomes described in section 3 of the Standard. NZFSA will approve these industry codes of practice for use by the sector concerned provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved.

1.0 Development and application of Hazard identification and analyses or HACCP Plans

All Hazard Identification and Analyses 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" (ftp://ftp.fao.org/codex/standard/en/CXP_001e.pdf). Excerpts from this document are included in this Appendix as ***bold italics***.

Additionally, a useful guideline to the application of HACCP can be obtained from the following:

- 1) NZFSA Food: Dairy operational guideline, "Dairy HACCP Plan Guideline" provides information to assist in meeting the outcomes required by this Standard. A copy of this guideline can be obtained from the NZFSA website (www.nzfsa.govt.nz/dairy/publications/guidelines/).
- 2) "Food Quality and Safety System – A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System (see Codex website: www.fao.org/docrep/W8088E/w8088e00.htm).

2.0 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. Prerequisite programmes are documented systems covering GMP-based food hygiene activities that have the potential to influence the hygiene status of the product and/or control hazards. Therefore, prior to implementation of a HACCP Plan, there is a requirement for the organisation to develop and implement applicable prerequisite programmes.

In addition to the HACCP Plan requirements, supporting systems should be developed when necessary to complement the HACCP Plan. These are simply tools that form part of the overall HACCP Plan but do not directly influence the hygiene status of the product and/or control hazards. This includes, for example, but is not limited to:

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

2.1 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.

2.2 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?).

3.0 Describe product

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.

4.0 Identify intended use/ 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 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 microorganisms.

4.1 Product safety outcomes

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

5.0 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.

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. Where trials have the potential to impact on mainstream processes, the impact should also be subject to a hazard analysis.

6.0 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.

7.0 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).

7.1 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.

Identify the hazard source and be specific in terms of the actual hazard. The level of specificity is determined by the extent of hazard identification required to ensure effective hazard control. (e.g. for raw milk instead of writing "biological hazard" be more specific and write "pathogenic bacteria, such as *E coli*, *Listeria spp*, *Salmonella spp*, *Staphylococcus aureus*"). This will ensure that the control measures are relevant and effective in controlling the specific hazard(s) identified.

7.2 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 effects; (see footnote1)**
- **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.**

Once all potential hazards that are reasonably likely to occur have been identified, analyse each hazard and decide which are significant in relation to the designated product outcome. A significant hazard is one that is likely to occur at unacceptable levels.

7.3 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 reasonably likely to occur, list the control measures or prerequisite programmes that are in place. Control measures are specific to the process step where the hazard has been identified whereas prerequisite programmes control hazards that could come into contact with product and are more generic in nature.

A control measure/prerequisite programme must be effective in controlling the specific hazard(s) identified, implemented and working on a consistent basis. Where control is not effective the HACCP team should determine the gaps and implement controls as necessary.

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

8.0 Determine Critical Control Points (SEE PRINCIPLE 2)

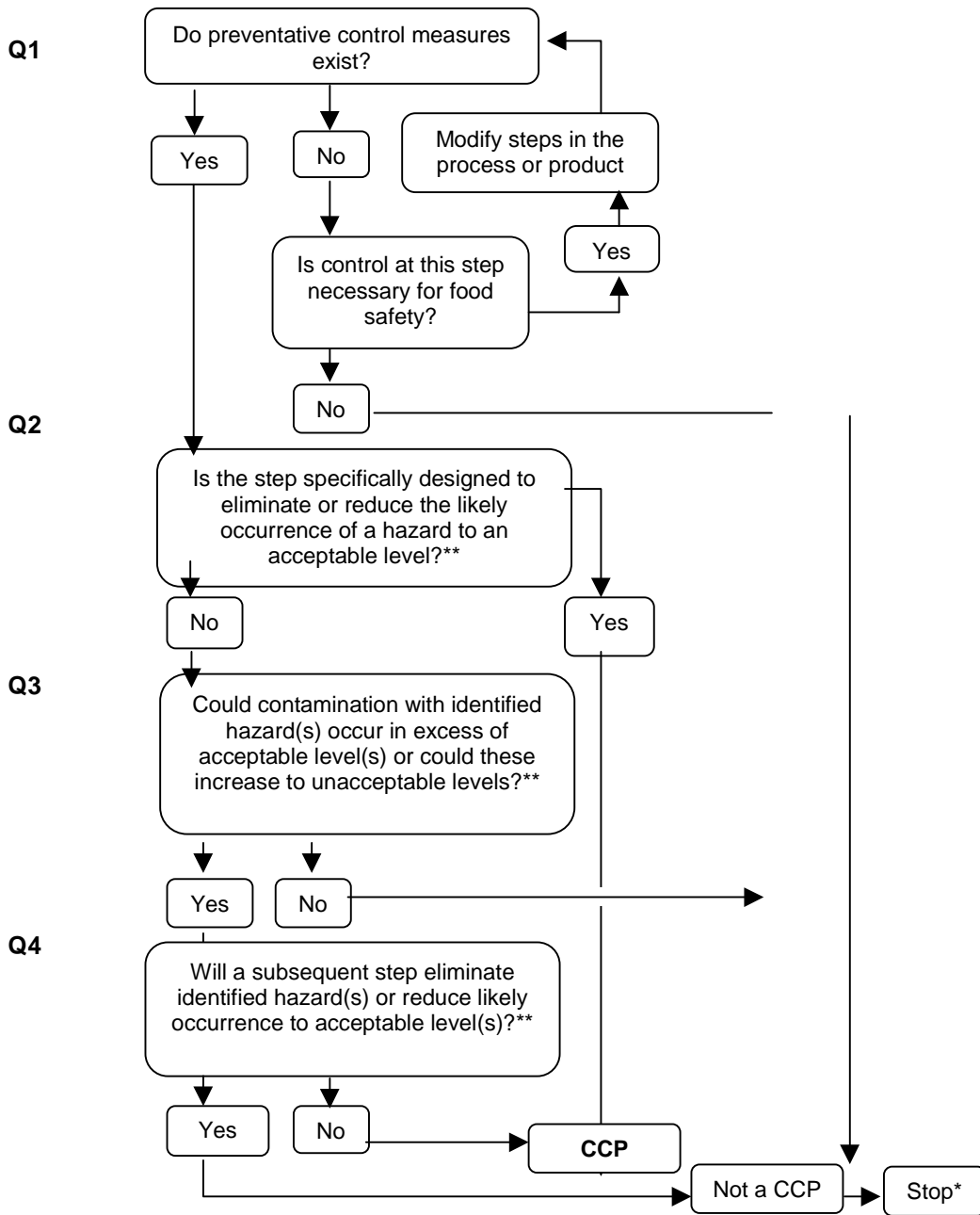
There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree [e.g. Figure A1.1], which indicates a logic reasoning approach. Application of a decision tree should be flexible, 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.

CCP's can be identified by means other than the Codex Decision Tree, as long as meaningful analysis of each identified significant hazard is undertaken in relation to expected product outcomes for the product.

The existence or non-existence of a CCP should never be assumed without working through some systematic decision making process.

Figure A1.1 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.

9.0 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.

When the critical limits for a critical control point have been met, the process and/or product is deemed to be safe at that point in the process because the product outcomes have been met. Consequently, where critical limits are exceeded, then the process or product may be deemed to be 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. Validation of critical limits proves product outcomes are achieved.

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. compliant with product outcomes.

10.0 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.

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.

11.0 Establish (CPP) 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 action responsibilities should be defined in the HACCP Plan, and recorded.

12.0 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.

The internal verification procedures 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.

12.1 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. The Hazard Identification and Analysis 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;

- 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 crack tests, divert 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.

(NB. CCP monitoring and CCP corrective action apply to a HACCP plan only)

12.2 HACCP system audits (internal only)

HACCP system audits should review the actual practices and application of any procedures written in the Hazard Identification and Analyses or HACCP Plans. HACCP system audits may include on-site observations to confirm that events are occurring. These may include confirmation that:

- product description and process flow diagram continue to be accurate;
- monitoring required by the HACCP Plan at the CCPs is performed;
- processes are operating within established critical limits;
- where monitoring has indicated a deviation from critical limits, affected product has been controlled as established and corrective actions have been followed;
- records are filled out accurately.

The audits may cover the entire Hazard Identification and Analyses or HACCP Plans or selected parts. However a full review is recommended periodically to ensure that the Hazard Identification and Analyses 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 Analyses or HACCP Plans

Additionally, a review of the HACCP system should occur when changes that may impact on the Hazard Identification and Analyses 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 Hazard Identification and Analyses or HACCP Plans may be undertaken following customer complaints.

12.3 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.

12.4 Product sampling and testing

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. Guidance for establishing the sampling and testing regime is available in the NZFSA HACCP guideline.

13.0 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".

14.0 Implementation

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.

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.

Co-operation 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.

Then the following points are recommended:

- external assessment of the Hazard Identification and Analyses or HACCP Plans.
- evaluation of Hazard Identification and Analyses or HACCP Plans
 - The validated Hazard Identification and Analyses or HACCP Plan is evaluated by NZFSA 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".
- external verification of Hazard Identification and Analyses or 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".

CIG/ TPA

**TPA's are independent and are monitored by the CIG.
CIG have internal systems to calibrate themselves.**

15.0 Reporting

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

Appendix Two: Importing Country Requirements

It is the responsibility of exporters to identify and comply with all importing country requirements; non-compliance is at their commercial risk.

Importing country requirements, which have been officially confirmed, can be obtained from the Dairy and Plant Products Group of NZFSA or its website (www.nzfsa.govt.nz/Dairy).

Where NZFSA provides official assurances to competent authorities of importing countries, the statements to which NZFSA attests must be verifiable. Relevant requirements are described in MAF Standard D206, "Dairy Sanitary and Related Export Certification".